UNITED STATES DISTRICT COURT EASTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA, and THE STATE OF WISCONSIN, ex rel. DR. TOBY TYLER WATSON,

Plaintiffs,

v. Case No. 11-CV-236

JENNIFER KING VASSEL,

Defendant.

DEFENDANT JENNIFER KING VASSEL'S BRIEF IN OPPOSITION TO THE PLAINTIFF'S MOTION FOR ENTRY OF AN HIPAA QUALIFIED PROTECTIVE ORDER FOR CUSTODIANS OF DR. KING'S PATIENT RECORDS

The plaintiff's request is not as straightforward as he presents. In short, the plaintiff's motion misleads the court in its focus on the compendia while ignoring the statutes that permit prescription medication reimbursement based on formularies developed by the State and its contracted insurers, or based on prior authorization. Moreover, the plaintiff fails to identify in what manner his request to medical records custodians would be provided. The plaintiff is requesting records from unnamed medical records custodians to analyze numerous volumes covering an eight year span of time for the three formularies that comprise the compendia, and compare them to the medical records of Dr. King in order to meet the directives of his proposed order. The plaintiff's motion should be denied. Defendant Jennifer King Vassel (Dr. King) respectfully submits this brief in opposition to the plaintiff's motion.

ARGUMENT

I. THE REIMBURSEMENT OF MEDICATION IS NOT DEFINED BY THE COMPENDIA.

The prescription of medication is not solely governed by reference to the compendia. 42 U.S.C. § 1396r-8(d)(1)(B)(I) states that "[a] State *may exclude or otherwise restrict coverage* of a covered outpatient drug if (I) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6) of this section) [...] or (iv) the State has excluded coverage of the drug from its formulary established in accordance with paragraph (4)." (emphasis added.) "A statute is not construed in a way that makes words or phrases meaningless, redundant, or superfluous." *Welsh v. Boy Scouts of America*, 993 F.2d 1267, 1272 (7th Cir. 1993) (citation omitted).

In other words, states have the option to provide coverage for drugs for which the prescribed use is not for a medically accepted indication; the limitations on coverage are not mandated, but are subject to the *discretion* of the State. A formulary, as noted in sub(iv) above, may be established by a State or its contracted insurer if it meets certain requirements. 42 U.S.C. § 1396r-8(d)(4); *see* Wis. Admin. Code DHS 107.10(1)(covered drugs include legend and non-legend drugs and supplies listed in the Wisconsin medicaid drug index); *see also Affidavit of Bradley S. Foley, Exhibit A*, Managed Health Services Preferred Drug List, revised April 2006. Of note, the administrative regulation does not mention the compendia at all.

The plaintiff's view of the Medicaid reimbursement statutes misleads in contending that the compedia is the sole source of reimbursement. This is contrary to the statutes and is incomplete. A prescription is approved for reimbursement pursuant to a formulary or prior authorization. *Affidavit of Jennifer King, M.D.*, \P 2. The plaintiff's request assumes something that is not true and must be denied.

II. THE PLAINTIFF FAILS TO IDENTIFY IN WHAT MANNER MEDICAL RECORDS CUSTODIANS WOULD BE ABLE TO DETERMINE THE INFORMATION TO BE PROVIDED.

The plaintiff's request would have medical records custodians evaluate each record from March 3, 2005 to the present, determine whether the prescription written by Dr. King, was, in fact, presented to Medicaid, and determine whether the prescription has any support in three formularies that comprise the compendia, over an eight year period of time. 42 U.S.C. § 1396r-8(g)(1)(B). These compendia contain thousands of pages of dense pharmaceutical and medical data. *Affidavit of Bradley S. Foley, Exhibit B, American Hospital Formulary Service Drug Information (AHFS) for 2004*, cover page, the entry for Clonidine (alleged in the complaint that it was a false claim in November 2004), and last page of the book. For example, the AHFS Drug Information book for 2004 alone is 3,731 pages. *Id.* And that is only for one year.

The plaintiff also assumes that the prescription was in fact presented by a pharmacy to Medicaid for reimbursement. The plaintiff, however, has not stated that he is requesting any records from any pharmacy, on which basis he could determine whether any medication was reimbursed by Medicaid or a health management organization (HMO) that contracted with Medicaid. This is significant, as the plaintiff refuses to see any information as to whether any prescription written by Dr. King was reimbursed as meeting the formulary of Medicaid or an HMO. If the prescription was reimbursed by the Medicaid HMO or Medicaid, then the plaintiff's claim lacks a basis in law. 31 U.S.C. § 3729(a)(1).

Unlike Dr. King's recently filed motion requesting authorization to access specifically named health care providers that provided care to N.B. during the time period alleged in the complaint, no such restrictions exist here. The plaintiff does not list *any* records custodian to who he would submit his proposed order. *See* Document 124-1, p. 2. The plaintiff is not simply asking medical records custodians to provide medical records; instead he is asking medical records custodians to make

medical judgments about whether a certain medical record is supported by the compendia. The plaintiff does not cite to any factual or legal support in his brief that a record custodian can engage in this analysis.

CONCLUSION

Based on the foregoing arguments, defendant Jennifer King Vassel respectfully requests that the Court deny the plaintiff's motion.

Dated at Milwaukee, Wisconsin this 29th day of October, 2013.

GUTGLASS, ERICKSON, BONVILLE & LARSON, S.C.

s/ Bradley S. Foley
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UNITED STATES DISTRICT COURT EASTERN DISTRICT OF WISCONSIN

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STATE OF WISCONSIN)			
COUNTY OF MILWAUKEE) ss.			
BRADLEY S. FOLEY, being duly sworn under	r oath, deposes and states as follows:		
1. I am one of the attorneys representing de	efendant Jennifer King Vassel in the above-		
referenced action and am authorized to make this affida	avit on her behalf.		
2. Attached as Exhibit A is a true and accu	rate copy of the Managed Health Services		
Preferred Drug List, revised April 2006.			
3. Attached as Exhibit B is a true and accu	rate copy of the American Hospital		
Formulary Service Drug Information (HAFS) for 2004	cover page, the entry for Clonidine (alleged		
in the complaint that it was a false claim in November	2004), and last page of the book.		
s/Bradley Bradley S			

Subscribed and sworn to before me this 29th day of October, 2013.

s/Carrie Wentland

Notary Public, State of Wisconsin My Commission expires: 1/19/14

Managed Health Services (MHS) Preferred Drug List

Revised 4/2006



MHS and MHS/NHP refer to the Medicaid/BadgerCare/SSI members of Managed Health Services and Network Health Plan



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Managed Health Services Pharmacy Program

Managed Health Services (MHS) covers prescription drugs and certain over-the-counter drugs when ordered by a doctor. Some medications require prior authorization (PA).

Working with our pharmacy benefit managers (PBMs)

MHS works with two PBMs.

Caremark is the preferred provider of biopharmaceuticals and injectables for MHS. US Script (formerly BioScrip/ScripSolutions) administers all other prescribed drugs.

Certain drugs require PA to be approved for payment by MHS. These include:

- All medications not listed on the MHS Preferred Drug List (PDL)
- Some MHS preferred drugs (designated by PA on the PDL)
- Most injectables costing over \$100, including Procrit, Neulasta and Neupogen. (Injectable cancer medications with indications limited to chemotherapy do not require PA.)

Slightly different guidelines for obtaining prior authorization are in place for the two PBMs.

Caremark - Biopharmaceuticals and Injectables

Caremark is the preferred provider of biopharmaceuticals and injectables for MHS.

Most injectables require PA to be approved for payment. Our medical director oversees the clinical review. Follow these guidelines for the most efficient processing of your prior authorization requests:

- 1. Complete two forms:
 - the MHS Request for Prior Authorization: Injectables, and the
 - CAREMARK Enroll for RX Form (This is the prescription order)
- 2. Fax both completed forms to MHS at (414) 921-1718
- 3. Once the request is approved, MHS staff will notify you by phone or fax, and provide an authorization number.
- 4. The request is not approved until you receive a PA number.

US Script (formerly BioScrip/ScripSolutions) — All Other Prescriptions

With the exceptions of biopharmaceuticals and injectables, US Script administers all prescribed drugs for MHS.

All medications not listed on the MHS Preferred Drug List (PDL) and some MHS preferred drugs require prior authorization to be approved for payment.

Follow these quidelines efficient processing of your prior authorization requests:

- 1. Complete the MHS/US Script form:
 - Request for Prior Authorization: Medication
- 2. Fax to US Script at 1-866-399-0929
- 3. Once approved, US Script notifies the prescriber by fax.
- 4. If the clinical information provided does not explain the medical necessity for the requested PA medication, US Scrip responds to the prescriber by fax, offering PDL alternatives.
- 5. For urgent or after-hours requests, a pharmacy can provide up to a 72-hour supply of medication by calling 1-800-460-8988.

We help keep you informed

The MHS Pharmacy Program director, a registered pharmacist, compiles current pharmacological policy and information about important seasonal topics such as Respiratory Syncytial Virus (RSV) and influenza. The information is consistent with published guidelines and is mailed to network providers as a service. The most current MHS preferred drug list can be downloaded from our website at www.mhswi.com.

The MHS Preferred Drug List (PDL)

The MHS PDL describes the circumstances under which contracted pharmacy providers will be reimbursed for medications dispensed to members covered under the program.

The PDL does not:

- a) Require or prohibit the prescribing or dispensing of any medication
- b) Substitute for the independent professional judgment of the physician/clinician or pharmacist, or
- c) Relieve the physician/clinician or pharmacist of any obligation to the patient or others

Pharmacy and Therapeutics Committee

The MHS Pharmacy and Therapeutics Committee continually evaluates the therapeutic classes included in the PDL. The committee is composed of the MHS medical director, pharmacist and several community-based primary care physicians and specialists.

The primary purpose of the committee is to assist in developing and monitoring the MHS PDL and to establish programs and procedures that promote the appropriate and cost-effective use of medications.

The P&T committee schedules meetings at least twice yearly, and coordinates reviews with a national P&T committee which meets an additional 4 times a year.

Unapproved Use of Preferred Medication

Medication coverage under this program is limited to non-experimental indications as approved by the FDA. Other indications may also be covered if they are accepted as safe and effective using current medical and pharmaceutical reference texts and evidence-based medicine. Reimbursement decisions for specific non-approved indications will be made by MHS in accordance with the procedures outlined in Section III. Experimental drugs, investigational drugs and drugs used for cosmetic purposes are not eligible for coverage.

Prior Authorization Process

The MHS PDL includes a broad spectrum of brand name and generic drugs. Clinicians are encouraged to prescribe from the MHS PDL for their patients who are members of MHS and Medicaid and BadgerCare members of NHP.

Some preferred drugs require PA. Medications requiring PA are listed with a "PA" notation throughout the PDL, including the index. In addition, all injectable medications (except Insulin, Glucagon Kit, Epi-pen, Ana-Kit, Imitrex, and Depo-Provera) require PA.

The P & T committee has reviewed and approved, with input from its members and in consideration of medical evidence, the list of drugs requiring prior authorization. This PDL attempts to provide appropriate and cost-effective drug therapy to all participants covered under the MHS pharmacy program. If a patient requires medication that does not appear on the PDL, the clinician can make a prior authorization request for a non-preferred medication. It is anticipated that such exceptions will be rare and that PDL medications will be appropriate to treat the vast majority of medical conditions.

A phone or fax-in process is available for PA requests.

US Script Contacts

Prior Authorization Fax

866-399-0929

Prior Authorization Phone

866-399-0928

Clinical Hours

M-F: 10 am-7pm (Central Time)

Mail address

US Script

2425 W Shaw Ave Fresno, CA 93711 When calling, please have patient information, including Medicaid number, complete diagnosis, medication history and current medications readily available.

Upon receipt of all necessary information, US Script will respond by fax or phone within 24 hours except during weekends and holidays.

If the request is approved, information in the on-line pharmacy claims processing system will be changed to allow the specific member to receive this specific drug. If the request is denied, information about the denial will be provided to the clinician.

Clinicians are requested to utilize the PDL when prescribing medication for those patients covered by the MHS pharmacy program. If a pharmacist receives a prescription for a drug that requires a prior authorization request, the pharmacist should attempt to contact the clinician to request a change to a product included in the PDL.

Phone Numbers for MHS Member Services

The above phone and fax lines are dedicated to clinicians requesting PA medication items only. Members cannot be assisted if they call the PA toll-free number.

MHS Member Services (888) 713-6180 (Phone) (414) 345-4649 (Fax)

72-Hour Emergency Supply Policy

State and Federal law require that a pharmacy dispense a 72-hour (3-day) supply of medication to any patient awaiting a PA determination. The purpose is to avoid interruption of current therapy or delay in the initiation of therapy. All participating pharmacies are authorized to provide a 72-hour supply of medication and will be reimbursed for the ingredient cost and dispensing fee of the 72-hour supply of medication, whether or not the PA request is ultimately approved or denied.

The pharmacy must call the US Script Pharmacy Help Desk at 800-460-8988 for a prescription override to submit the 72-hour medication supply for payment.

Specific Exclusions

The following drug categories are not part of the MHS PDL and **are not covered by the 72-hour emergency supply policy:**

- Allergy immunotherapy
- Biopharmaceuticals
- · Blood and blood plasma
- Cosmetic drugs
- DESI drugs
- Diagnostic products (except those listed in the PDL)
- · Experimental drugs
- Fertility drugs
- · Immunological agents and vaccines
- Impotence drugs
- Injectables (except for in-home use administered by patient)
- Medical supplies and durable medical equipment (except those listed in the PDL)
- Nutritional and dietary supplements
- OTC products (except those listed in the PDL)
- · Topical minoxidil

Newly Approved Products

Newly Approved drug products will not normally be placed on the preferred drug list during their first six months on the market. During this period, access to these medications will be considered through the PA review process.

Step Therapy

Medications requiring step therapy are listed with an "ST" notation throughout the preferred drug list. Preferred drugs that currently require step therapy are:

- · Accolate previous therapy with albuterol or steroid inhaler.
- Elidel previous therapy with topical steroids.
- Singulair previous therapy with albuterol or steroid inhaler.
- Xopenex previous therapy with aerosolized albuterol.

Tablet Splitting

Zoloft 50mg = Zoloft 100mg (1/2 tablet)
Zoloft 25mg = Zoloft 50mg (1/2 tablet)
citalopram 20mg = citalopram 40mg (1/2 tablet)
citalopram 10mg = citalopram 20mg (1/2 tablet)
Lexapro 10mg = Lexapro 20mg (1/2 tablet) requires PA
Lexapro 5mg = Lexapro 10mg (1/2 tablet) requires PA

The MHS claims system will automatically check the member profile for evidence of prior or current usage of the required agent. If there is evidence of the required agent on the member's profile, the claim will automatically process. If not, the claims system will notify the pharmacist that a PA is required.

Policy for Injectable Drugs

Injections that are self-administered by the member and/or a family member and appear on the PDL are covered by the MHS pharmacy program. Insulin, Glucagon Kit, Epi-pen, Ana-Kit, Imitrex, and Depo-Provera are covered by MHS and do not require a PA.

All other injectables require PA.

Dispensing Limits - Quantity and Age

All drugs may be dispensed up to a maximum 30-day supply. A total of 80 percent (80%) of the days supplied must have elapsed before the prescription can be refilled, i.e., a prescription can be refilled after 24 days.

Medications with a quantity limit are listed with a "QL" notation throughout the PDL. Medications with an age limit are listed with an "AL" notation throughout the PDL. The drugs listed below have quantity or age limits.

Quantity Limits

(Not all drugs listed have PDL status. Please refer to the index for the PDL listings.)

- Aciphex® max 30 tablets per month
- Advair Diskus® max 1 diskus (60 inhalations) per month
- Albuterol max 1 unit per month
- Aldara® max 1 kit per month
- Allegra® max 30 tablets per month
- Ambien® max 30 tablets per month
- Amerge® max 9 tablets per month
- Amphetamine/Dextroamphetamine ER max 30 tablets/capsules per month
- Anzemet® max 1 tablet per month
- Apap/Codeine 325mg-15mg, 325mg-30mg, 325mg-60mg max 180 tablets per month
- Apap/Hydrocodone 325mg-10mg, 500mg -5mg, 500mg -7.5mg, 650mg -10mg max 180 tablets per month
- Apap/Hydrocodone 750mg-7.5mg max 120 tablets per month
- Apap/Oxycodone 325mg-5mg, 500mg-7.5mg, 650mg-10mg max 180 tablets per month
- Aspirin/Oxycodone 325mg-4.5mg max 180 tablets per month
- Atrovent® max 1 unit per month
- Avinza® max 30 capsules per month

- Axert® max 6 tablets per month
- Azmacort® Inhaler max 1 unit per month
- Bupropion SR max 60 tablets per month
- Celebrex® max 60 capsules per month
- Clarinex® max 30 tablets per month
- Combivent® max 1 unit per month
- Crestor® max 30 tablets per month
- Depo-Provera® Contraceptive Suspension 150mg (1ml) every 90 days
- Dovonex® max 60gm or 60ml per month
- Effexor XR® max 30 capsules per month
- Elidel® max 60gm per month (requires PA)
- Epipen®, Epipen Jr.® max. 1 unit per fill
- Fentanyl lollipop max 30 per month
- Fentanyl patches max 10 per month
- Flovent® max 1 unit per month
- Foradil® max 1 unit per month
- Frova® max 9 tablets per month
- Geodon® max 60 capsules per month
- Glucagon Kit max 1 kit per month
- Imitrex® Injection Kit max 2 kits per month
- Imitrex® Nasal Spray max 6ml per month
- Imitrex® Oral Tablet max 9 tablets per month
- Kadian® max 30 capsules per month
- Kytril® max 2 tablets per month
- Lescol XL® max 30 tablets per month
- Lipitor® max 30 tablets per month
- Loratadine 10mg Tablets max 30 tablets per month
- Loratadine Syrup max 300ml per month
- Loratadine w/Pseudoephedrine 12 hr Tablets max 60 tablets per month
- Loratadine w/Pseudoephedrine 24 hr Tablets max 30 tablets per month
- Lovastatin max 30 tablets per month
- Lunesta® max 30 tablets per month
- Maxair® max 1 unit per month
- Maxalt® max 12 (5mg); 6 (10mg) tablets per month
- Methadone 5mg, 10mg max 120 tablets per month
- Methylphendidate CR, ER, SR max 30 tablets/capsules per month
- Migranal® max 2 units per month
- Miralax® max 255gm per month
- MS Contin® (generic) max 60 tablets per month
- Nexium® max 30 capsules per month
- Nicotine gum max 2 boxes per month for 3 months lifetime benefit
- Nicotine Patch, Transdermal max 30 patches per month for 3 months lifetime benefit
- · Ofloxacin otic soln max 5ml per treatment
- Omeprazole max 30 capsules per month (requires PA)
- Ortho-Evra® Patch 3 patches per 28 days
- Oxycodone 5mg max 180 tablets per month
- OxyContin CR® max 60 tablets per month (requires PA)
- Pravachol® max 30 tablets per month

- Prevacid® max 30 capsules per month
- Protonix® max 30 tablets per month (requires PA)
- Provigil® max 60 tablets per month
- Pulmicort Inhaler® max 120 max 1 unit per month
- Pulmicort Pulvules® max 120 pulvules (total 1mg per day)
- Relenza® max 1 unit per month
- Relpax® max 6 tablets per month
- Risperdal Consta® max 2 syringes per month
- Rozerem® max 30 tablets per month
- Serevent Diskus® max 1 diskus (60 inhalations) per month
- Simvastatin max 30 tablets per month (applies to all statins)
- Sonata® max 30 capsules per month
- Spirva® handihaler max I unit per month
- Stadol® max 2 units (5cc) per month
- Strattera max 30 capsules per month (requires PA)
- Tamiflu® max 10 capsules per month
- Toradil® max 10 tablets per month
- Tramadol max 120 tablets per month
- Vytorin® max 30 tablets per month
- Wellbutrin XL® max 30 tablets per month
- Xopenex® HFA max 15 gm per month
- Xopenex® Nebulizer Solution max 288ml per month (requires PA)
- Zetia ® max 30 tablets per month
- Zofran® 24mg Tablet 1 tablet per treatment
- Zofran® 4, 8mg Tablets max 10 tablets per month
- Zofran® Solution max 50ml per month
- Zomig/Zomig ZMT® max 6 tablets per month
- Zomig® nasal spray max 6 units per month
- Zyban SR® max 60 tablets per month for 3 months lifetime benefit
- Zyrtec® max 30 tablets per month
- Zyrtec® Syrup max 300ml per month (requires PA)

Age Limits:

Ages 3 - 18 years only

- Amphetamine/Dextroamphetamine, SR
- · Dextroamphetamine, SR
- Methylphenidate, CR, ER, SR

Age < 3 years old only

Diflucan® Suspension

Age < 9 years old only

Pulmicort Respules®

Age < 12 years old only

Zyrtec® Syrup

Age < 21 years old only

 OTC drugs covered through HealthCheck "Other Services"

Age < 21 years old, males only

- Ferrous sulfate OTC
- Ferrous gluconate OTC

Age < 35 years old only

Retin A®

Age < 50 years old, females only

- · Prenatal vitamins with FA
- Ferrous sulfate OTC
- Ferrous gluconate OTC

Mandatory Generic Substitution

MHS requires that generic substitution be made when a generic equivalent is available. All branded products that have an A-rated generic equivalent will be reimbursed at the maximum allowable cost price.

The provision is waived for the following products due to their narrow therapeutic index:

Aminophylline, Amiodarone, Carbamazepine, Clozapine, Cyclosporine, Digoxin, Disopyramide, Ethosuximide, Flecainide, L-thyroxine, Lithium, Phenytoin, Procainamide, Propafenone, Theophylline, Thyroid, Valproate Sodium, Valproic Acid, Warfarin.

Over-The-Counter Medications

The pharmacy program covers a large selection of over-the-counter medications (OTC). All covered OTC's appear in the PDL. **All OTC medications must be written on a valid prescription,** by a licensed physician/clinician, in order to be reimbursed.

DESI or LTE Drugs

DESI drug products and known related drug products are defined as less than effective by the Food and Drug Administration, because there is a lack of substantial evidence of effectiveness for all labeling indications and because a compelling justification for their medical need has not been established. State programs may allow coverage of certain DESI drugs. Any DESI drugs that are covered by MHS are listed in the MHS PDL.

Contacts for Pharmacy Appeals/Grievances

Members

In the event that a member disagrees with the decision regarding coverage of a medication, the member may file a grievance with MHS by calling a MHS member advocate at (888) 713-6180 (Phone) or (414) 345-4649 (Fax).

Physicians / clinicians

In the event that a clinician or member disagrees with the decision regarding coverage of a medication, the clinician may request reconsideration by submitting additional information to US Script. The additional information may be provided verbally or in writing. A decision will be rendered by a US Script clinical pharmacist and the clinician will be notified with a faxed response. If the denial is upheld, the clinician will be notified of the appeal process at that time.

In the event that a clinician or member disagrees with the decision of the clinical pharmacist, the clinician may file a written appeal to the Clinical Coordinator at US Script. Additional information and/or supporting documentation should be included with the request. US Script will notify the clinician in writing with the standard appeal decision. A decision will be rendered within three (3) business days of receipt of complete information.

If the denial is upheld, the clinician will be notified of the MHS appeal process.

An expedited appeal may be requested at any time the provider believes the adverse determination might seriously jeopardize the life or health of a member. A response will be rendered within the same day as receipt of complete information. In certain circumstances that require research, consultation with the US Script Medical Advisor and/or literature review, a same day response may not be possible. A 72-hour emergency supply of the medication will be provided to the patient until the expedited appeal review is completed.

In the event that the clinician or member disagrees with the appeal decision of the US Script Clinical Coordinator, the clinician may then appeal this decision in writing to the MHS Medical Director via fax at (414) 921-1718.

Annotations

PA = This medication requires prior authorization

ST = This medication requires step therapy

QL = This medication is limited to a specific quantity

AL = This medication is limited to a specific patient age

I. ANTI-INFECTIVE AGENTS

AMINOGLYCOSIDES

neomycin sulfate (generic Mycifradin)

tablet: 500mg

paromomycin (Humatin) PA

capsule: 250mg

ANTIFUNGALS

fluconazole (generic Diflucan)

tablet: 150mg

tablet: 50, 100, 200

suspension: 10mg/ml, 40mg/ml

griseofulvin microsize (generic Grifulvin V)

suspension: 125mg/5ml tablet: 125, 250, 500mg ultra tablet: 125, 250mg

griseofulvin ultramicrosize (generic Gris-PEG)

tablet: 165, 250mg

ketoconazole (generic Nizoral)

tablet: 200mg

nystatin (generic Mycostatin)

suspension: 100,000U/5ml

tablet: 500,000U

ANTIHELMINTICS

mebendazole (generic Vermox)

chewable tab: 100mg

thiabendazole (generic Mintezol)

chewable tab: 500mg suspension: 500mg/5ml

ANTIMALARIAL

chloroquine phosphate (generic Aralen)

tablet: 500mg

dapsone (Dapsone)

tablet: 25, 100mg

hydroxychloroquine (generic Plaquenil)

tablet: 200mg

I. ANTI-INFECTIVE AGENTS cont'd

ANTIMALARIAL cont'd

mefloquine (Lariam)

tablet: 250mg

primaquine phosphate (Primaquine)

tablet: 26.3mg

quinine sulfate (generic Quinamm)

capsule: 200, 300, 325mg

tablet: 260mg

ANTITUBERCULOSIS

ethionamide (Trecator)

tablet: 250mg

isoniazid (generic INH)

syrup: 50mg/5ml

tablet: 50, 100, 300mg

pyrazinamide (generic pyrazinamide)

tablet: 500mg

rifampin (generic Rifadin)

capsule: 150, 300ma

ANTIVIRALS

abacavir sulfate (Ziagen)

solution: 20mg/ml tablet: 300mg

abacavir/lamivudine (Epzicom)

tablet: 600-300mg

abacavir/lamivudine/zidovudine (Trizivir)

tablet: 300mg-150mg-300mg

acyclovir (generic Zovirax)

capsule: 200mg

suspension: 200mg/5ml

tablet: 400, 800mg

amantadine (generic Symmetrel)

capsule: 100mg

syrup: 50mg/5ml

atazanavir (Reyataz)

capsule: 100, 150, 200mg

I. ANTI-INFECTIVE AGENTS cont'd

ANTIVIRALS cont'd

amprenavir (Agenerase)

capsule: 50, 150mg solution: 15mg/ml

ddC/dideoxycytidine (Hivid)

tablet: 0.375, 0.75mg

ddl/dideoxyinosine (Videx)

chewable tab: 25, 50, 100, 150, 200mg EC capsule: 125, 200, 250, 400mg

oral solution: 2, 4gm

sachet: 100, 167, 250, 375mg

delavirdine mesylate (Rescriptor)

tablet: 100, 200mg

efavirenz (Sustiva)

capsule: 50, 100, 200, 600mg

emtricitabine (Emtriva)

capsule: 200mg

emtricitabine/tenofovir (Truvada)

tablet: 200-300mg

fosamprenavir (Lexiva)

tablet: 700mg

ganciclovir (Cytovene)

capsule: 250, 500mg

indinavir (Crixivan)

capsule: 100, 200, 333, 400mg

lamivudine (Epivir)

oral solution: 10mg/ml tablet: 150, 300mg

lamivudine/zidovudine (Combivir)

tablet: 150mg-300mg

Iopanavir/ritonavir (Kaletra)

capsule: 133.3mg-33.3mg solution: 400mg-100mg/5ml

nelfinavir mesylate (Viracept)

powder: 50mg/gm tablet: 250mg

I. ANTI-INFECTIVE AGENTS cont'd

ANTIVIRALS cont'd

nevirapine (Viramune)

suspension: 50mg/5ml

tablet 200mg

retrovir (AZT/zidovudine)

capsule: 100mg syrup: 50mg/5ml tablet: 300mg

ritonavir (Norvir)

capsule: 100mg

oral solution: 80mg/ml

saquinavir (Fortovase)

capsule: 200mg

saquinavir mesylate (Invirase)

capsule: 200mg

stavudine (Zerit)

capsule: 15, 20, 30, 40mg oral solution: 1mg/ml

tenofovir (Viread)

tablet: 300mg

valacyclovir (Valtrex)

tablet: 500mg, 1000mg

CEPHALOSPORINS

cefacior (generic Ceclor)

capsule: 250, 500mg

suspension: 125mg/5ml, 187mg/5ml,

375mg/5ml

cefdinir (Omnicef)

suspension: 125mg/5ml, 250mg/5ml

cefditoren (spectracef)

tablet: 200mg

cefprozil (Cefzil)

suspension: 125mg/5ml, 250mg/5ml

cefuroxime (generic Ceftin)

tablet: 250, 500mg

suspension: 125mg/5ml, 250mg/5ml

I. ANTI-INFECTIVE AGENTS cont'd

CEPHALOSPORINS cont'd

cephalexin (generic Keflex) capsule: 250, 500mg

suspension: 125mg/5ml, 250mg/5ml

MACROLIDES

azithromycin (Zithromax)

capsule: 250mg (Z-pak) powder pack: 1gm pack

suspension: 100mg/5ml, 200mg/5ml

tablet: 500 x 3 (Tri-Pak)

tablet: 600mg

clarithromycin (generic Biaxin)

suspension: 125mg/5ml, 187.5mg/5ml,

250mg/5ml

tablet: 250, 500mg

clindamycin (generic Cleocin)

capsule: 150, 300mg

clindamycin palmitate (Cleocin Pediatric)

suspension: 75mg/5ml

erythromycin base (generic E-Mycin)

EC tablet: 250, 500mg

erythromycin ethylsuccinate (generic E.E.S.)

chewable tab: 200mg drop: 100mg/2.5ml granule: 200mg/5ml

suspension: 200mg/5ml, 400mg/5ml

tablet: 400mg

erythromycin stearate (generic Erythrocin)

tablet: 250, 500mg

MISCELLANEOUS ANTI-INFECTIVES

metronidazole (generic Flagyl)

tablet: 250, 500mg

nitrofurantoin microcrystals (generic

Macrodantin)

capsule: 50, 100mg

I. ANTI-INFECTIVE AGENTS cont'd

MISCELLANEOUS ANTI-INFECTIVES cont'd

trimethoprim (generic Proloprim)

tablet: 100mg

PENICILLINS

amoxicillin (generic Amoxil)

capsule: 250, 500mg

chewable tab: 125, 250, 400mg

drop: 50mg/ml

suspension: 125mg/5ml, 250mg/5ml,

400mg/5ml tablet: 875mg

amoxicillin/potassium clavulanate (generic

Augmentin)

chewable tab: 125, 200, 250, 400mg suspension: 200mg/5ml, 400mg/5ml

ES suspension: 600mg/5ml tablet: 250, 500, 875mg

XR tablet: 1gm

ampicillin (generic Principen)

capsule: 250, 500mg

suspension: 125mg/5ml, 250mg/5ml

dicloxacillin (generic Dycill)

capsule: 250mg

suspension: 62.5mg/5mg

penicillin VK (generic PenVee K)

suspension: 125mg/5ml, 250mg/5ml

tablet: 125, 250, 500mg

QUINOLONES

ciprofloxacin (generic Cipro)

cystitis pack: 100mg tablet: 250, 500, 750mg

levafloxacin (Levaquin)

tablet: 250, 500, 750mg

SULFONAMIDES

sulfasalazine (generic Azulfidine)

tablet: 500mg

I. ANTI-INFECTIVE AGENTS cont'd

SULFONAMIDES cont'd

sulfisoxazole (Gantrisin) suspension: 500mg/5ml

trimethoprim/sulfamethoxazole (generic

Septra)

suspension; 40mg-200mg/5ml

tablet: 80mg-400mg DS-tablet: 160mg-800mg

TETRACYCLINES

doxycycline (generic Vibramycin)

capsule: 50, 100mg tablet: 50, 100 mg

minocycline (generic Minocin)

capsule: 50, 75, 100mg

tetracycline (generic Achromycin V)

capsule: 250, 500mg

II. ANTINEOPLASTICS & IMMUNOSUPPRESSANTS

ANTINEOPLASTIC

altretamine (Hexalen)

capsule: 50mg

anastrozole (Arimidex)

tablet: 1mg

bexarotene (Targretin)

capsule: 75mg

bicalutamide (Casodex)

tablet: 50mg

busulfan (Myleran)

tablet: 2mg

capecitabine (Xeloda)

tablet: 150, 500mg

chlorambucil (Leukeran)

tablet: 2mg

II. ANTINEOPLASTICS & IMMUNOSUPPRESSANTS cont'd

ANTINEOPLASTIC cont'd

cyclophosphamide (generic Cytoxan)

tablet: 25, 50mg

estramustine (Emyct)

capsule: 140mg

etoposide (Vepesid)

capsule: 50mg

exemestane (Aromastin)

tablet: 25mg

fluorouracil (Efudex)

cream: 0.5% solution: 2%, 5%

flutamide (generic Eulexin)

capsule: 125mg

hydroxyurea (generic Hydrea)

capsule: 500mg

imatinib (Gleevec)

capsule: 100mg

letrozole (Femara)

tablet: 2.5mg

leucovorin calcium (generic leucovorin)

tablet: 5, 10, 15, 25mg

Iomustine (CeeNU)

capsule: 10, 40, 100mg

megestrol acetate (generic Megace)

suspension: 40mg/ml

tablet: 20, 40mg

melphalan (Alkeran)

tablet: 2mg

mercaptopurine (Purinethol)

tablet: 50mg

methotrexate (generic methotrexate)

tablet: 2.5mg

II. ANTINEOPLASTICS & IMMUNOSUPPRESSANTS cont'd

ANTINEOPLASTIC cont'd

mitotane (Lysodren) tablet: 500mg

nilutamide (Nilandron) tablet: 50, 150mg

procarbazine (Matulane) capsule: 50mg

tamoxifen citrate (generic Nolvadex) tablet: 10, 20mg

temozolomide (Temodar)

capsule: 5, 20, 100, 250mg

testolactone (Teslac) tablet: 50mg

thioguanine (Thioguanine) tablet: 40mg

toremifine citrate (Fareston) tablet: 60mg

tretinoin (Vesanoid) capsule: 10mg

IMMUNOSUPPRESSANTS

azathioprine (generic Imuran) tablet: 50mg

cyclosporine (generic Neoral) gel capsule: 25, 100mg

cyclosporine (generic Sandimmune) capsule: 25, 100mg

mycophenolate mofetil (Cellcept)

capsule: 250mg powder: 200mg/ml tablet: 500mg

mycophenolate mofetil extended-release

(Myfortic)

tablets: 180, 360mg

II. ANTINEOPLASTICS & IMMUNOSUPPRESSANTS cont'd

IMMUNOSUPPRESSANTS cont'd

sirolimus (Rapamune) solution: 1mg/ml tablet: 1, 2mg

tacrolimus (Prograf) capsule: 0.5, 1, 5mg

III. CENTRAL NERVOUS SYSTEM

ANTIDEPRESSANTS

amitriptyline (generic Elavil) tablet: 10, 25, 50, 75, 100, 150mg

bupropion (generic Wellbutrin) tablet: 75, 100mg

bupropion SR (Wellbutrin-SR) SR tablet: 100, 150, 200mg

citalopram (generic Celexa) solution: 10mg/5ml tablet: 10, 20, 40mg

desipramine (generic Norpramine) tablet: 25, 50, 75, 100, 150mg

doxepin (generic Adapin, generic Sinequan) capsule: 10, 25, 50, 75, 100mg

fluoxetine (generic Prozac) capsule: 10, 20mg liquid: 20mg/5ml

fluvoamine (generic Luvox) tablet: 25, 50, 100mg

imipramine (generic Tofranil) tablet: 10, 25, 50mg

mirtazapine (generic Remeron)

tablet: 15, 30mg

nortriptyline (generic Aventyl, generic Pamelor) capsule: 10, 25, 50, 75mg

III. CENTRAL NERVOUS SYSTEM cont'd

ANTIDEPRESSANTS cont'd

paroxetine (generic Paxil) tablet: 10, 20, 30, 40mg

phenelzine (Nardil) tablet: 15mg

sertraline (Zoloft) solution: 20mg/ml tablet: 25, 50, 100mg

tranylcypromine (Parnate) tablet: 10mg

trazodone (generic Desyrel) tablet: 50, 100, 150mg

venlafaxine (Effexor, Effexor-XR) QL tablet: 25, 37.5, 50, 75, 100mg XR capsules: 37.5, 75, 150mg

ANTIMANIA

divalproex (Depakote) tablet: 125, 250, 500mg capsule: 125mg sprinkle

divalproex ER (Depakote ER) ER tablet: 250, 500mg

lithium carbonate (generic Eskalith) capsule: 300mg

lithium carbonate (Lithobid) SR tablet: 300mg

lithium carbonate CR (Eskalith-CR)
CR tablet: 450mg

ANTIPSYCHOTICS

aripiprazole (Abilify) tablet: 5, 10, 15, 20, 30mg oral solution: 1mg/ml

chlorpromazine (generic Thorazine) concentrate: 30mg/ml, 100mg/ml tablet:10, 25, 50, 100, 200mg

III. CENTRAL NERVOUS SYSTEM cont'd

ANTIPSYCHOTICS cont'd

clozapine (generic Clozaril) tablet: 25, 100mg

fluphenazine (generic Prolixin) concentrate: 5mg/ml, 2.5mg/5ml tablet: 1, 2.5, 5, 10mg

haloperidol (generic Haldol) concentrate: 2mg/ml tablet: 0.5, 1, 2, 5, 10mg

loxapine (generic Loxitane) capsule: 5, 10, 25, 50mg

olanzapine (Zyprexa) tablet: 2.5, 5, 7.5, 10, 15, 20mg

perphenazine (generic Trilafon) concentrate: 16mg/5ml tablet: 2, 4, 8, 16mg

perphenazine w/amitriptyline (generic Triavil) tablet: 2/10mg, 2/25mg, 4/10mg, 4/25mg, 4/50mg

quetiapine (Seroquel) tablet: 25, 100, 200, 300mg

risperidone (Risperdal) solution: 1mg/ml tablet: 0.25, 0.5, 1, 2, 3, 4mg

thiothixene (generic Navane) capsule: 1, 2, 5, 10mg concentrate: 5mg/ml

trifluoperazine (generic Stelazine) tablet: 1, 2.5, 5, 10mg

ziprasidone (Geodon) QL=60 capsule: 20, 40, 60, 80mg

ANXIOLYTICS, SEDATIVES & HYPNOTICS

alprazolam (generic Xanax) tablet: 0.25, 0.50, 1, 2mg

III. CENTRAL NERVOUS SYSTEM cont'd

ANXIOLYTICS, SEDATIVES & HYPNOTICS cont'd

buspirone (generic Buspar) tablet: 5, 7.5, 10, 15, 30mg

chlordiazepoxide (generic Librium) capsule: 5, 10, 25mg

clonazepam (generic Klonopin) tablet: 0.5, 1, 2mg

clorazepate (generic Tranxene) tablet: 3.75, 7.5, 15mg

diazepam (generic Valium) tablet: 2, 5, 10mg

Iorazepam (generic Ativan) tablet: 0.5, 1, 2mg

oxazepam (generic Serax) capsule: 10, 15, 30mg

phenobarbital (generic Luminal)

elixir: 20mg/5ml

tablet: 15, 30, 60, 100mg

temazepam (generic Restoril) capsule: 7.5, 15, 30mg

zolpidem (Ambien) QL=30 tablet: 5, 10mg

CEREBRAL STIMULANTS

amphetamine/dextroamphetamine (generic Adderall) AL

tablet: 5, 10, 15, 20, 30mg (age 3-18 years only)

amphetamine/dextroamphetamine ER (Adderall-XR) AL, QL=30

ER capsule: 5, 10, 15, 20, 25, 30mg (age 3-18 years only)

atomaxetine (Strattera) PA, QL capsule: 10, 18, 25, 40, 60mg

III. CENTRAL NERVOUS SYSTEM cont'd

CEREBRAL STIMULANTS cont'd

dextroamphetamine (generic Dexedrine) AL tablet: 5,10mg (age 3-18 years only)
SR capsule: 5, 10, 15mg (age 3-18 years only)

methylphenidate (generic Ritalin) AL tablet: 5,10, 20mg (age 3-18 years only)

methylphenidate CR (Concerta, Metadate-CD) AL, QL=30

CR tablet: 18, 27, 36, 54mg (age 3-18 years only)
CR capsule: 20, 40, 50, 60mg (age 3-18

years only)

methylphenidate SR (generic Ritalin SR, Methylin ER) AL, QL=30

ER tablet: 10, 20mg (age 3-18 years only) SR tablet: 20mg (age 3-18 years only)

CHOLINESTERASE INHIBITORS

donepezil (Aricept) tablet: 5,10mg

IV. NEUROMUSCULAR AGENTS

ANTICONVULSANTS

carbamazepine (generic Tegretol)

chewable tab: 100mg

tablet: 200mg

suspension: 100mg/5ml

carbamazepine SR (Tegretol XR) SR tablet: 100, 200, 400mg

clonazepam (generic Klonopin) tablet: 0.5, 1, 2mg

divalproex (Depakote)

ER tablet: 250, 500mg tablet: 125, 250, 500mg capsule: 125mg sprinkle

IV. NEUROMUSCULAR AGENTS cont'd

ANTICONVULSANTS cont'd

ethosuximide (Zarontin)

capsule: 250mg syrup: 250mg/5ml

felbamate (Felbatol)

suspension: 600mg/5ml tablet: 400, 600mg

gabapentin (generic Neurontin) PA

capsule: 100, 300, 400mg solution: 250mg/5ml tablet: 600, 800mg

lamotrigene (Lamictal)

chewable tab: 5, 25mg tablet: 125, 100, 150, 200mg

levatiracetam (Keppra)

tablet: 250, 500, 750mg

oxcarbazepine (Trileptal)

suspension: 300mg/5ml tablet: 150, 300, 600mg

phenobarbital (generic Luminal)

elixir: 20mg/5ml

tablet: 8, 16, 32, 60, 100mg

phenytoin (Dilantin)

capsule: 30, 100mg chewable tab: 50mg

suspension: 50mg/5ml, 125mg/5ml

primidone (generic Mysoline)

suspension: 250mg/5ml

tablet: 50, 250mg

tiagabine (Gabitril)

tablet: 2, 4, 12, 16mg

topiramate (Topamax) PA

capsule: 15, 25mg

tablet: 25, 50, 100, 200mg

IV. NEUROMUSCULAR AGENTS cont'd

ANTICONVULSANTS cont'd

valproic acid (generic Depakene)

capsule: 250mg syrup: 250mg/5ml

ANTIMYASTHENIC AGENTS

pyridostigmine bromide (generic Mestinon)

tablet: 60, 180mg

riluzole (Rilutek) PA tablet: 50mg

ANTIPARKINSONS

amantadine (generic Symmetrel)

capsule: 100mg

benztropine mesylate (generic Cogentin)

tablet: 0.5, 1, 2mg

bromocryptine mesylate (Parlodel)

capsules: 5mg tablet: 2.5mg

carbidopa/levodopa (generic Sinemet)

tablet: 10/100mg, 25/100mg, 25/250mg

CR tablet: 25/100, 50/200mg

levodopa (Larodopa)

tablet: 100, 250, 500mg

selegiline (generic Eldepryl)

capsules: 5mg tablet: 5mg

trihexyphenidyl (generic Artane)

elixir: 0.4mg/ml tablet: 2, 5mg

MUSCLE RELAXANTS

baclofen (generic Lioresal)

tablet: 10, 20mg

carisoprodol (generic Soma)

tablet: 350mg

IV. NEUROMUSCULAR AGENTS cont'd

MUSCLE RELAXANTS cont'd

cyclobenzaprine (generic Flexeril)

tablet: 10mg

dantrolene (Dantrium)

capsule: 25, 50, 100mg

diazepam (generic Valium)

tablet: 2, 5, 10mg

methocarbamol (generic Robaxin)

tablet: 500, 750mg

V. ENDOCRINE & METABOLIC DRUGS

ANDROGENS

fluoxymesterone (generic Halotestin)

tablet: 2, 5, 10mg

methyltestosterone (Methitest)

tablet: 10mg

testosterone patch (Androderm)

patch: 2.5, 5mg/24 hours

ANTIDIABETIC

glimepiride (Amaryl)

tablet: 1, 2, 4mg

glipizide (generic Glucotrol)

tablet: tablet: 5,10mg (NO XL)

glyburide (generic Diabeta, generic Micronase)

tablet: 1.25, 2.5, 5mg

glyburide/metformin (Glucovance)

tablet: 2.5/250mg, 2.5/500mg

human insulin (Humulin, Novolin)

100U/ml /10ml vial

human insulin aspart (Novolog)

100U/ml /10ml vial

V. ENDOCRINE & METABOLIC DRUGS cont'd

ANTIDIABETIC cont'd

human insulin glargine (Lantus)

100U/ml /10ml vial

human insulin lispro (Humalog)

100U/ml /10ml vial

metformin (generic Glucophage)

tablet: 500, 850, 1000mg (NO XR)

pioglitazone (Actos)

tablet: 15, 30mg

rosiglitazone (Avandia)

tablet: 2, 4, 8mg

roiglitazone/metformin (Avandamet)

tablet: 2mg/500mg, 4mg/500mg

ANTITHYROIDS

methimazole (generic Tapazole)

tablet: 5,10mg

propylyhiouracil (generic PTU)

tablet: 50mg

CONDOMS & SPERMICIDES

All condoms and spermicides are covered.

OTC

CONTRACEPTIVES

Apri (generic Desogen)

tablet: 0.15mg/30mcg

Enpresse (generic Triphasil)

tablet: 0.05mg/30mcg, 0.075mg/40mcg,

0.125mg/30mcg

ethinyl estradiol/etonogestrel (Nuvaring)

ring: 12mcg/0.015mg

Kariva (generic Mircette)

tablet: 0.15mg/20mcg

Lessina (generic Alesse)

tablet: 0.1mg/20mcg

V. ENDOCRINE & METABOLIC DRUGS cont'd

CONTRACEPTIVES cont'd

Levora (generic Nordette) tablet: 0.15/30mcg

Low-Ogestrel (generic Lo/Ovral) tablet: 0.3mg/30mcg

Necon (generic Norinyl)

tablet: 1mg/35mcg, 1mg/50mcg

norelgestromin/ethinyl estradiol (Ortho Evra)
OL

patch: 0.15mg/20mcg (max=3 patches per 28 days)

norethindrone (generic Nor-QD)

tablet: 0.35mg

norethindrone/ethinyl estradiol (Estrostep Fe)

tablet: 1mg/20mcg, 1mg/30mcg, 1mg/

35mcg

norethindrone/ethinyl estradiol (generic

Ovcon)

tablet: 0.4mg/35mcg, 1mg/50mcg

norethindrone/ethinyl estradiol (Tri-Norinyl)

tablet: 0.5mg/35mcg, 1mg/35mcg, 0.5mg/35mcg

norethindrone/ethinyl estradiol (generic

Ortho 777)

tablet: 0.5 mg/35mcg, 0.75mg/35mcg, 1mg/

35mcg

norgestrel (Ovrette)

tablet: 0.075mg

Nortel (generic Brevicon, generic Modicon)

tablet: 0.5mg/35mcg

Ogestrel (generic Ovral)

tablet: 0.5mg/50mcg

Sprintec (generic Ortho Cyclen)

tablet: 0.25 mg/35mcg

V. ENDOCRINE & METABOLIC DRUGS cont'd

CONTRACEPTIVES cont'd

tri-sprintec (generic Ortho Tri-Cyclen) tablet: 0.18, 0.215, 0.25mg/35mcg

Zovia (generic Demulen)

tablet: 1mg/35mcg, 1mg/50mcg

CORTICOSTEROIDS-ORAL

cortisone acetate (generic Cortisone) tablet 25mg

dexamethasone (generic Decadron)

elixir: 0.5mg/5ml

tablet: 0.25, 0.5, 0.75, 1.5, 2, 4, 6mg

fludrocortisone (generic Florinef)

tablet: 0.1mg

hydrocortisone (generic Cortef)

tablet: 20mg

methylprednisolone (generic Medrol)

dose pak: 4mg tablet: 4mg

prednisolone (generic Pediapred)

liquid: 6.7mg/5ml solution: 15mg/5ml

prednisolone (generic Prelone)

syrup: 5mg/5ml, 15mg/5ml

prednisone (generic Deltasone) tablet: 1, 2.5, 5, 10, 20, 50mg

DIABETIC TESTING SUPPLIES

Blood Glucose Monitoring Kits

FS System

Freestyle Kit Flash

One Touch Basic

One Touch Ultra

One Touch Ultra Smart

V. ENDOCRINE & METABOLIC DRUGS cont'd

DIABETIC TESTING SUPPLIES cont'd

Precision Kit

Surestep Kit

Blood Testing Strips and Lancets

Fasttake testing strips

Freestyle testing strips and lancets

One Touch testing strips and lancets

One Touch Ultra testing strips

Penlet lancet device

Precision teststrips

Precision Extra teststrips

Surestep testing strips

Thin lancets (Abbott)

Insulin Syringes

B-D, Sure-Dose

Miscellaneous - Diabetic Supplies

Glucose Tab. Urine Test Strips, Urine Test Tab

DIAPHRAGMS

Ortho All-Flex

various sizes

ESTROGENS

conjugated estrogen (Premarin)

tablet: 0.3, 0.45, 0.625, 0.9, 1.25, 2.5mg vaginal cream: 0.625mg/gm

conjugated estrogens/medroxyprogesterone

(Prempro)

tablet: 0.3/1.5mg, 0.45/1.5mg, 0.625/2.5mg, 0.625/5mg

V. ENDOCRINE & METABOLIC DRUGS cont'd

ESTROGENS cont'd

estradiol (generic Climara)

patch: 0.05, 0.075, 0.1, 0.25mg

estradiol (generic Estrace)

tablet: 0.5, 1mg

estradiol/norethindrone (Combipatch)

patch: 0.05/0.14, 0.05/0.25

estropipate (generic Ogen)

tablet: 0.625, 1.25, 2.5mg

MISCELLANEOUS ENDOCRINE

alendronate (Fosamax) PA

tablet: 5, 10, 70mg

calcitonin (Miacalcin NS)

nasal spray: 2001U

desmopressin acetate (generic DDAVP)

nasal solution: 0.01%, 2.5 and 5ml

nasal spray: 0.01% 5ml

tablet: 0.1, 0.2mg

raloxifene (Evista)

tablet: 60mg

OXYTOCICS

methylergonovine (Methergine)

tablet: 0.2mg

PROGESTINS

medroxyprogesterone (generic Provera)

tablet: 2.5, 5, 10mg

medroxyprogesterone depot (generic Depo-

Provera) QL

injection: 150mg/ml (max=1ml per 90 days)

norethindrone acetate (Aygestin)

tablet: 5mg

V. ENDOCRINE & METABOLIC DRUGS cont'd

THYROID REPLACEMENTS

levothyroxine (generic Levoxyl, generic

Synthroid)

tablet: 0.025, 0.05, 0.075, 0.088, 0.1, 0.112,

0.125, 0.137, 0.15, 0.175, 0.2, 0.3mg

liotrix (Thyrolar)

tablet: 15, 30, 60, 120, 180mg

thyroid (generic Armour Thyroid)

tablet: 0.25, 0.5, 1, 1.5, 2, 3, 4, 5gr

VI. CARDIOVASCULARS

ANTIANGINALS

isosorbide dinitrate (generic Isordil)

SL tablet: 2.5, 5, 10mg

SR tablet: 40mg

tablet: 5, 10, 20, 30mg

isosorbide mononitrate (generic Imdur)

tablet: 30, 60, 120mg

nitroglycerin (Nitrostat)

ointment: 2%

SL tablet: 0.3, 0.4, 0.6mg

nitroglycerin patch (generic Nitro-Dur)

patch: 0.1, 0.2, 0.3, 0.4, 0.6, 0.8mg/hr

ANTIARRHYTHMICS

amiodarone (generic Cordarone)

tablet: 200mg

digoxin (Lanoxin)

elixir: 0.05mg/ml

tablet: 0.125, 0.25, 0.5mg

disopyramide (generic Norpace)

capsule: 100, 150mg

disopyramide CR (generic Norpace CR)

CR capsule: 150mg

VI. CARDIOVASCULARS cont'd

ANTIARRHYTHMICS cont'd

flecainide (generic Tambocor)

tablet: 50, 100, 150mg

moricizine (Ethmozine)

tablet: 200, 250, 300mg

procainamide (generic Pronestyl)

capsule: 250, 375, 500mg

SR tablet: 250, 500, 750mg, 1gm

propafenone (generic Rhythmol)

tablet: 150, 225, 300mg

quinidine gluconate (generic Quinaglute)

tablet: 324mg

quinidine sulfate (generic Quinidex)

tablet: 100, 200, 300mg

tocainide (Tonocard)

tablet: 400, 600mg

ANTIHYPERLIPIDEMICS

cholestyramine (generic Questran)

packets, powder

gemfibrozil (generic Lopid)

tablet: 600mg

Iovastatin (generic Mevacor) QL=30

tablet: 20, 40mg

niacin, controlled-release (Slo-Niacin) OTC

tablet: 500, 750, 1000mg

simvastatin (generic Zocor) QL=30

tablet: 10, 20, 40, 80mg (max=30 per

month)

ANTIHYPERTENSIVES

ACE Inhibitors and Combinations

benazepril (generic Lotensin)

tablet: 5, 10, 20, 40mg

VI. CARDIOVASCULARS cont'd

ANTIHYPERTENSIVES cont'd

benazepril/HCTZ (generic Lotensin HCT) tablet: 5/6.25mg, 10/12.5mg, 20/12.5mg, 20/25mg

captopril (generic Capoten) tablet: 12.5, 25, 50, 100mg

captopril/HCTZ (generic Capozide) tablet: 25/15mg, 25/25mg, 50/15mg, 50/ 25mg

enalapril (generic Vasotec) tablet: 2.5, 5, 10, 20mg

enalapril/HCTZ (generic Vasoretic) tablet: 5/12.5mg, 10/25mg

lisinopril (generic Zestril) tablet: 2.5, 5, 10, 20, 30, 40mg

lisinopril/HCTZ (generic Zestoretic) tablet: 10/12.5mg, 20/12.5mg, 20/25mg

trandolopril (Mavik) tablet: 1, 2, 4mg

Angiotensin Receptor Blockers (ARB)

losartan (Cozaar) tablet: 25, 50, 100mg

Iosartan/HCTZ (Hyzaar)

tablet: 12.5/50mg, 12.5/100mg, 25/100mg

olmesartan (Benicar) tablet: 5, 20, 40mg

olmesartan/HCTZ (Benicar HCT) tablet: 12.5/20, 12.5/40, 25/40mg

valsartan (Diovan) tablet: 40, 80, 160, 320mg

Sympatholytics & Vasodilators

clonidine (generic Catapres) tablet: 0.1, 0.2, 0.3mg

VI. CARDIOVASCULARS cont'd

ANTIHYPERTENSIVES cont'd

doxazosin (generic Cardura) tablet: 1, 2, 4, 8mg

guanabenz acetate (generic Wytensin) tablet: 4, 8mg

guanfacine (generic Tenex)
tablet: 1, 2mg

methyldopa (generic Aldomet) tablet: 250, 500mg

prazosin (generic Minipres)
tablet: 1, 2, 5mg

terazosin (generic Hytrin) capsule: 1, 2, 5, 10mg

BETA BLOCKERS

atenolol (generic Tenormin) tablet: 25, 50, 100mg

atenolol/chlorthalidone (generic Tenoretic) tablet: 50/25mg, 100/25mg

carvedilol (Coreg) tablet: 3.125, 6.25, 12.5, 25mg

labetalol (generic Normodyne) tablet: 100, 200, 300mg

metoprolol (generic Lopressor) tablet: 50, 100mg

nadolol (generic Corgard) tablet: 20, 40, 80, 120, 160mg

propranolol (generic Inderal) tablet: 10, 20, 40, 60, 80, 90mg

propranolol CR (Inderal LA) capsule: 60, 80, 120, 160mg

propranolol/HCTZ (generic Inderide) tablet: 40/25mg, 80/25mg

VI. CARDIOVASCULARS cont'd

CALCIUM CHANNEL BLOCKERS

amlodipine (Norvasc) tablet: 2.5, 5, 10mg

amlodipine/benazepril (Lotrel) tablet: 2.5/10mg, 5/10mg, 5/20mg

diltiazem (generic Cardizem) tablet: 30, 60, 90, 120mg

diltiazem ER (generic Dilacor XR) capsule: 120, 180, 240mg/24hr

diltiazem ER (generic Cardizem CD) capsule: 120, 180, 240,300mg/24hr

diltiazem SR (generic Cardizem SR) capsule: 60, 90, 120mg/12hr

felodipine (generic Plendil) tablet: 2.5, 5, 10mg

nifedipine (generic Procardia) capsule: 10, 20mg

nifedipine ER (generic Adalat CC, generic Procardia XL) tablet: 30, 60, 90mg

verapamil (generic Calan, generic Isoptin) tablet: 40, 80, 120mg

verapamil CR (generic Calan SR, generic Isoptin SR) tablet: 120, 180, 240mg

DIURETICS

acetazolamide (generic Diamox) tablets: 125, 250mg

bumetanide (generic Bumex) tablet: 0.5, 1.0, 2mg

chlorthalidone (generic Hygroton) tablet: 25, 50, 100mg

VI. CARDIOVASCULARS cont'd

DIURETICS cont'd

furosemide (generic Lasix) tablet: 20, 40, 80mg

solution: 10mg/ml, 40mg/5ml

hydrochlorothiazide (generic Hydrodiuril)

tablet: 25, 50, 100mg

indapamide (generic Lozol) tablet: 1.25, 2.5mg

metozalone (generic Zaroxolyn) tablet: 2.5, 5, 10mg

spironolactone (generic Aldactone) tablet: 25, 50, 100mg

spironolactone/HCTZ (generic Aldactazide) tablet: 25/25mg, 50/50mg

triamterene/HCTZ (generic Dyazide, generic Maxzide)

capsule: 50mg/25mg tablet: 37.5/25mg, 75/50mg

ANTICOAGULANTS & BLOOD MODIFIERS

clopidogrel (Plavix) PA tablet: 75mg

dipyridamole (generic Persantine) tablet: 25, 50, 75mg

pentoxifylline (generic Trental) tablet: 400mg

warfarin (Coumadin)

tablet: 1, 2, 2.5, 3, 4, 5, 6, 7.5, 10mg

VII. RESPIRATORY AGENTS

ANTIASTHMATICS

albuterol (Proventil) QL

MDI: 90mcg/puff solution: 5mg/ml

solution for inhalation: 0.083%

syrup: 2mg/5ml tablet: 2, 4mg

VII. RESPIRATORY AGENTS cont'd

ANTIASTHMATICS cont'd

albuterol/ipratropium (Combivent) QL

MDI: 90mcg/18mcg/puff

formoterol (generic Foradil) QL

powder capsules for inhalation

ipratropium bromide (generic Atrovent) QL

inhalation solution: 0.02%

MDI: 18mcg/puff

Ievalbuterol (Xopenex) QL, ST

inhalation solution: 0.021%, 0.042%

(max=288ml per month)

metaproterenol (generic Alupent)

MDI: 65mcg/puff

metaproterenol (generic Metaprel)

solution for inhalation: 0.4, 0.6, 5%

syrup: 10mg/5ml tablet:10, 20mg

pirbuterol (Maxair) QL

MDI: 0.2mg Autohaler

salmeterol (Serevent Diskus) QL

diskus: 50mcg/dose (max=1diskus per

month)

terbutaline (generic Brethine)

tablets: 2.5/5mg

theophylline (Slo-Phylline)

elixir: 80 mg/15ml solution: 80mg/15ml tablet: 100, 200mg

theophylline SR (Theophylline SR)

capsule: 125/300mg

tablet: 125, 200, 300, 450mg

theophylline SR (Uniphyl)

tablet: 400, 600mg

tiotropium (Spiriva) QL

powder for inhalation (capsules)

VII. RESPIRATORY AGENTS cont'd

ANTIHISTAMINE/DECONGESTANT COMBINATIONS

bpm/pseudoephedrine (generic Bromfed,

generic Rondec)

capsule: 12mg/120mg, 6mg/60mg

syrup: 4mg/45mg/5ml tablet: 4mg/60mg

chlorpheniramine/pseudoephedrine (generic

Deconamine)

chewable tab: 1mg/15mg SR tablet: 8mg/120mg syrup: 2mg/30mg/5ml tablet: 4mg/60mg

cpm/phenylephrine/methoscopolamine

(generic Extendryl)

chewable tab: 2/10/1.25mg CR tablet: 8/20/2.5mg syrup: 2/10/1.25mg/5ml

cpm/phenylephrine/pyrilamine (generic

Rynatan-S)

suspension: 2mg/5mg/12.5mg/5ml

phenylephrine, chlorpheniramine, dextromethorphan (generic Rondec DM

Drops)

solution: 3.5/1/3mg/ml

phenylephrine, chlorpheniramine, dextromethorphan (Trital DM, Corfen DM,

Norel DM)

syrup: 10/4/15mg/5ml

pseudoephedrine (generic Sudafed) OTC

tablet; 30, 60mg

pseudoephedrine/guaifenesin (generic

Zephrex LA)

tablet: 120/500mg, 90/600mg, 120/600mg

triprolidine/pseudoephedrine (generic

Actifed) **OTC** tablet: 2/30mg

VII. RESPIRATORY AGENTS cont'd

ANTIHISTAMINES

cetirizine (Zyrtec) QL, AL, PA

syrup: 5mg/5ml (max= 300ml per month), (age limit <12)

chlorpheniramine (generic Chlor-Trimeton) **OTC**

tablet: 4, 8mg solution: 2mg/5ml

cyproheptadine (generic Periactin)

syrup: 2mg/5ml tablet: 4mg

dexchlorpheniramine (generic Polaramine)

CR tablet: 4mg, 6mg syrup: 2mg/5ml

diphenhydramine (generic Benadryl)

capsule: 50mg

diphenhydramine (generic Benadryl) OTC

capsule: 25mg tablet: 25mg elixir: 12.5mg/5ml

hydroxyzine (generic Atarax)

syrup: 10mg/5ml tablet: 10, 25, 50mg

hydroxyzine pamoate (generic Vistaril)

capsule: 25, 50, 100mg

Ioratadine (generic Claritin) OTC, QL

syrup: 10mg/10ml (max=300ml per month) tablet: 10mg (max=30 per month)

OD tablet: 10mg (max=30 per month)

Ioratadine/pseudoephedrine (generic Claritin-D) OTC, QL

12 hr. tablet: 5mg/120mg (max=60 per month)

24 hr. tablet: 10mg/240mg (max=30 per

month)

VII. RESPIRATORY AGENTS cont'd

ANTITUSSIVES

benzonatate (generic Tessalon Perles)

capsule: 100mg

codeine/guaifenesin (generic Robitussin AC)

syrup: 10mg/100mg/5ml

codeine/promethazine (generic Phenergan w/

codeine)

syrup: 10mg/6.25mg/5ml

dextromethorphan/guaifenesin (generic

Humibid DM)

tablet: 30mg/600mg

Dextromethorphan/guaifenesin (generic

Diabetic Tussin DM, max. strength Diabetic

Tussin DM) OTC

liquid: 10mg/100mg/5ml liquid: 10mg/200mg/5ml

guaifenesin (generic Robitussin) OTC

syrup: 100mg/5ml

guaifenesin CR (generic Duratuss-G, generic

Humibid LA)

tablet: 600mg, 1200mg

hydrocodone/guaifenesin (generic Duratuss

HD) elixir:

hydrocodone/homatropine (generic Hycodan)

syrup: 5mg/5ml

promethazine/dextromethorphan (generic

Phenergan DM)

syrup: 6.25mg/100mg/5ml

pseudoephedrine/guaifenesin (generic

Deconsal II)

tablet: 60mg/600mg

phenylephrine/hydrocodone/guaifenesin

(generic Duratuss HD)

elixir: 10mg/2.5mg/225mg/5ml

VII. RESPIRATORY AGENTS cont'd

INHALED STEROIDS AND ANTI-INFLAMMATORIES

beclomethasone (Vanceril)

MDI: 42mcg/puff

beclomethasone dipropionate HFA (QVAR)

MDI: 40mcg/puff, 80mcg/puff

budesonide (Pulmicort) QL

pulvules: 0.25mg/ml, 0.5mg/ml AL<9

inhaler: 0.2mg/puff

cromolyn sodium (generic Intal)

solution: 20mg/2ml

cromolyn sodium (Intal)

MDI: 800mcg/puff

fluticasone propionate (Flovent) QL

MDI: 44mcg, 110mcg, 220mcg/puff

fluticasone/salmeterol (Advair Diskus) QL=1

diskus: 100/50, 250/50, 500/50mcg/puff

nedocromil (Tilade)

MDI: 1.75mg/puff

triamcinolone (Azmacort) QL

MDI: 100mcg/puff

INTRANASAL STEROIDS

beclomethasone (Beconase AQ)

nasal spray: 50mcg/puff

fluticasone (Flonase)

nasal spray: 50mcg/puff

mometasone furoate (generic Nasonex)

nasal spray: 50mcg/puff

triamcinolone (generic Nasacort AQ)

nasal spray: 55mcg/puff

VII. RESPIRATORY AGENTS cont'd

LEUKOTRIENE RECEPTOR ANTAGONISTS

montelukast (Singulair) ST

chewable tab: 4, 5mg

granules: 4mg tablet: 10mg

zafirlukast (Accolate) ST

tablet: 10, 20mg

SPACER DEVICES

Aerochamber

Aerochamber w/Mask

Easivent

EZ-spacer

EZ-spacer w/Mask

Inspirease

Optichamber

Optihaler

sterile normal saline (generic Bronchosaline)

OTC

VIII. GASTROINTESTINAL AGENTS

ANTIEMETICS

meclizine (generic Antivert)

tablet: 12.5, 25mg

ondansetron (Zofran ODT) QL

tablet: 4, 8mg (max=10 per month) tablet: 24mg (max=1 per treatment)

OD tablet: 4, 8mg (max=10 per month)

solution: 4mg/5ml (max=50ml per month)

prochlorperazine (generic Compazine)

suppository: 2.5, 5, 25mg

syrup: 5mg/5ml

tablet: 5, 10, 25mg

VIII. GASTROINTESTINAL AGENTS cont'd

ANTIEMETICS cont'd

promethazine (generic Phenergan)

suppository: 25, 50mg tablet: 12.5, 25, 50mg

ANTISPASMODIC & G.I. MOTILITY

dicyclomine (generic Bentyl)

capsule: 10mg tablet: 20mg

diphenoxylate/atropine (generic Lomotil)

liquid: 2.5mg/0.025mg/5ml tablet: 2.5mg/0.025mg

hyoscyamine sulfate (generic Levsin)

drop: 0.125mg/ml elixir: 0.125mg/5ml tablet: 0.125mg

hyoscyamine sulfate CR (generic Levsinex)

capsule: 0.375mg

kaolin-pectin (generic Kaopectate) OTC, AL suspension: 750mg/5ml (age limit <21)</p>

Ioperamide (generic Imodium AD) OTC, AL

capsule: 2 mg (age limit <21) liquid: 1mg/5ml (age limit <21)

metoclopramide (generic Reglan)

syrup: 5mg/5ml tablet: 5, 10mg

BOWEL PREPARATIONS

polyethylene glycol/electrolytes (generic

CoLyte)

solution: 4000ml

DIGESTANTS

lactase (Lactaid) OTC, AL

tablet: 3300 units (age limit <21)

lactase extra strength (Lactaid Extra Strength)

OTC, AL

tablet: 4500 units (age limit <21)

VIII. GASTROINTESTINAL AGENTS cont'd

DIGESTANTS cont'd

lactase ultra (Lactaid Ultra) OTC, AL chewtab: 9000 units (age limit <21)

tablet: 9000 units (age limit<21)

pancrelipase (Cotazym)

capsule: 30KU amylase/8KU lipase/30KU

protease

pancrelipase (generic Pancrease MT-10)

capsule: 30KU amylase/10KU lipase/30KU

protease

pancrelipase (generic Pancrease)

capsule: 20KU amylase/4KU lipase/25KU

protease

pancrelipase (generic Ultrase MT 18)

capsule: 58.5KU amylase/18KU lipase/

58.5KU protease

pancrelipase (generic Pancrease MT-16)

capsule: 48KU amylase/16KU lipase/48KU

protease

pancrelipase (generic Ultrase MT 20)

capsule: 65KU amylase/20KU lipase/65KU

protease

pancrelipase (generic Pancrease MT-20)

capsule: 56KU amylase/20KU lipase/44KU

protease

MISCELLANEOUS G.I. AGENTS

bisacodyl (generic Dulcolax) OTC, AL

suppository: 10mg (age limit <21)

tablet: 5mg (age limit <21)

bismuth subsalicylate (generic Pepto Bismol)

OTC

suspension: 262, 525mg/15ml

tablet: 262mg

castor oil USP (Castor Oil) OTC, AL

liquid: (age limit <21)

VIII. GASTROINTESTINAL AGENTS cont'd

MISCELLANEOUS G.I. AGENTS cont'd

docusate sodium (generic Colace) OTC, AL capsule: 100, 250mg (age limit <21) syrup: 60mg/15ml (age limit <21)

glycerin suppository USP (Glycerin Suppository) OTC, AL suppository: (age limit <21)

hydrocortisone acetate (generic Anusol-HC)

cream: 2.5% suppository: 25mg

hydrocortisone acetate/pramoxine

(Analpram-HC) cream: 1% lotion: 2.5%

hydrocortisone enema (generic Cortenema)

retention enema: 100mg/60ml

lactulose (generic lactulose) syrup: 10mg/15ml

magnesium citrate USP (Citrate of Magnesia)
OTC. AL

solution: 1.75gm/30ml (age limit <21)

magnesium hydroxide (Milk of Magnesia) OTC, AL

suspension: 400mg/5ml (age limit <21)

mesalamine (Asacol) tablet: 400mg

mesalamine (Pentasa) capsule: 250mg

mesalamine (Rowasa)

retention enema: 4gm/60ml

phosphate (Fleets Enema) OTC, AL enema: (age limit <21)

polyethylene glycol 335 (generic Miralax)
QL=255gm

VIII. GASTROINTESTINAL AGENTS cont'd

MISCELLANEOUS G.I. AGENTS cont'd

psyillium (generic Metamucil) OTC, AL powder: 3.4gm/dose (age limit <21)

senna (generic Ex-Lax) OTC, AL tablet: 15, 25mg (age limit <21)

senna (generic Senokot) OTC, AL tablet: 50mg (age limit <21)

simethicone (generic Mylicon) OTC

drops: 40mg/0.6ml tablet: 80mg

sulfasalazine (generic Azulfidine)

tablet: 500mg EN tablet: 500mg

ULCER TREATMENT & PREVENTION

alum. hydrox/mag. hydrox/simethicone (generic Mylanta) OTC

suspension: 200/225mg/5ml

alum. hydrox/mag. Hydroxide (generic Maalox) OTC

suspension: 200/225mg/5ml

cimetidine (generic Tagamet-HB) OTC tablet: 200mg

cimetidine (generic Tagamet) solution: 300mg/5ml tablet: 300, 400, 800mg

famotidine (generic Pepcid AC) OTC tablet: 10mg

mag. hydrox/calcium carbonate (generic Di-Gel) OTC

suspension: 225/500mg/5ml

omeprazole (Prilosec) OTC

tablet: 20mg

omeprazole (generic Prilosec) PA

capsule: 20, 40mg

VIII. GASTROINTESTINAL AGENTS cont'd

ULCER TREATMENT & PREVENTION cont'd

pantoprazole (Protonix) PA

tablet: 20, 40mg

ranitidine (generic Zantac-75) OTC

tablet: 75mg

ranitidine (generic Zantac)

tablet: 150, 300mg

ranitidine (Zantac Liquid)

syrup: 15mg/ml

IX. GENITOURINARY AGENTS

ANTI-INFECTIVES AND ANTISPASMODICS

bethanechol (Urecholine)

tablet: 5, 10, 25, 50mg

flavoxate (Urispas)

tablet: 100mg

methenamine (generic Mandelamine)

tablet: 0.5, 1gm

oxybutynin (generic Ditropan)

tablet: 5mg

phenazopyridine (generic Pyridium)

tablet: 100, 200mg

potassium citrate (Urocit-K)

tablet 540, 1080mg

tolterodine tartrate (Detrol)

tablet: 1, 2mg

LA capsule: 2, 4mg

VAGINAL PREPARATIONS

clotrimazole (generic Mycelex-7) OTC

vaginal cream: 1%

clotrimazole (generic Mycelex-3) OTC

vaginal cream: 2%

IX. GENITOURINARY AGENTS cont'd

VAGINAL PREPARATIONS cont'd

metronidazole (generic Metrogel)

vaginal gel: 0.75%

miconazole (generic Monistat-7) OTC

vaginal cream: 2% suppository: 100mg

miconazole (Monistat-3) OTC

vaginal cream: 4% suppository: 200mg

miconazole (generic Monistat-3 Combo Pack)

OTC

suppository: 200mg, 2% cream

miconazole (generic Monistat-1) OTC

vaginal ointment: 6.5%

miconazole (Monistat-1 Combo Pack) OTC

suppository: 1200mg, 2% cream

spermicidal cream (contraceptive cream) OTC

cream/suppositories

terconazole (generic Terazol-7)

vaginal cream: 0.4%

terconazole (generic Terazol-3)

vaginal cream: 0.8%

X. ANALGESICS AND ANESTHETICS

ANALGESICS

acetaminophen (generic Feverall) OTC

suppository: 80, 120, 325, 650mg

acetaminophen (generic Tylenol) OTC

chewtab: 80mg

drops: 80mg/0.8ml

tablet: 325, 500mg

elixir: 160mg/5ml

acetylsalacylic acid (generic aspirin) OTC

tablet: 81, 325mg

EC tablet: 325, 500mg

suppository: 60, 120, 200, 300, 600mg

X. ANALGESICS AND ANESTHETICS cont'd

ANALGESICS cont'd

apap/codeine (generic Tylenol w/codeine)
QL=180

elixir: 120mg - 12mg/5mg

tablet: 325mg-15mg, 325mg-30mg, 325mg-

60mg

apap/hydrocodone (generic Lorcet) QL=180

tablet: 650mg-10mg

apap/hydrocodone (generic Lortab) QL=180

elixir: 167mg-2.5mg/5ml

tablet: 500mg-5mg, 500mg-7.5mg

apap/hydrocodone (generic Vicodin)

ES tablet: 750mg-7.5mg QL=120 tablet: 500mg-5mg QL=180

apap/oxycodone (generic Percocet) QL=180

tablet: 325mg-5mg, 500mg-7.5mg, 650mg-

10mg

aspirin/oxycodone (generic Percodan) QL=180

tablet: 325mg-4.5mg

codeine sulfate (generic Codeine)

tablet: 15mg, 30mg, 60mg

fentanyl patch (generic Duragesic) PA, QL=10

patch: 25, 50, 75, 100mcg

hydromorpone (generic Dilaudid)

suppository: 3mg tablet: 1, 2, 3, 4, 8mg

ibuprofen (generic Advil) OTC

tablet: 200mg

suspension: 100mg/5ml

drops: 50mg/1.25ml

meperidine (generic Demerol)

syrup: 50mg/5ml tablet: 50, 100mg

methadone (generic Dolophine) QL=120

tablet: 5, 10mg

X. ANALGESICS AND ANESTHETICS cont'd

ANALGESICS cont'd

morphine sulfate (generic MSIR) solution: 10mg/5ml, 20mg/5ml

tablet: 15mg, 30mg

morphine sulfate (generic RMS)

suppository: 5, 10, 20, 30mg

morphine sulfate (generic Roxanol)

solution: 20mg/ml

morphine sulfate SR (MS Contin) QL=60

tablet: 15, 30, 60, 100, 200mg

naproxen sodium (generic Aleve) OTC

tablets: 220mg

oxycodone (generic OxyContin) PA, QL

tablet: 10, 20, 40, 80mg (max=60 per

month)

oxycodone (generic Roxicodone) QL=180

tablet: 5mg

propoxyphene napsylate/apap (generic

Darvocet-N)

tablet: 50/325mg, 100/650mg

tramadol (generic Ultram) QL=120

tablet: 50mg

ANTIGOUT

allopurinol (generic Zyloprim)

tablet: 100, 300mg

colchicine (Colchicine)

tablet: 0.5, 0.6mg

indomethacin (generic Indocin)

capsule: 25, 50, 75mg

probenecid (generic Benemid)

tablet: 500mg

X. ANALGESICS AND ANESTHETICS cont'd

ANTIRHEUMATICS

methotrexate (generic Rheumatrex)

tablet: 2.5mg

penicillamine (Cuprimine)

capsule: 125, 250mg

LOCAL ANESTHETICS

lidocaine (generic Xylocaine Viscous)

solution: 2%

MIGRAINE AND HEADACHE PRODUCTS

almotriptan (Axert) QL=6

tablet: 1, 2.5mg

apap/butalbital (generic Phrenylin)

capsule: 650/50mg tablet: 650/50mg

apap/caffeine/butalbital (generic Fioricet,

generic Esgic)

capsule, tablet: 325/40/50mg

apap/caffeine/butalbital (generic Esgic Plus)

tablet: 500/40/50mg

apap/caffeine/butalbital/codeine (generic

Fioricet w/codeine)

capsule: 325/40/50/30mg

aspirin/caffeine/butalbital (generic Fiorinal)

capsule, tablet: 325/40/50mg

ergotamine/caffeine (Cafergot)

tablet: 1/100mg

isomethheptene/dichloralphenazone/apap

(generic Midrin)

capsule: 65/100/325mg

sumatriptan (Imitrex) QL

injection kit: 6mg/0.5ml QL=2

nasal spray: 5mg/spray, 20mg/spray QL=6

tablet: 25, 50, 100mg QL=9

X. ANALGESICS AND ANESTHETICS cont'd

MIGRAINE AND HEADACHE PRODUCTS cont'd

zolmitriptan (Zomig) QL=6

nasal spray: 5mg/spray OD tablet: 2.5, 5mg tablet: 2.5, 5mg

NSAIDS

celecoxib (Celebrex) PA

capsule: 100, 200, 300mg

diclofenac (generic Voltaren)

tablet: 25, 50, 75mg

etodolac (generic Lodine)

capsule: 200, 300mg tablet: 400, 500mg

Ibuprofen (generic Advil) OTC

tablet: 200mg

Ibuprofen (generic Motrin)

tablet: 400, 600, 800mg

indomethacin (generic Indocin)

capsule: 25, 50, 75mg

nabumetone (generic Relafen)

tablet: 500, 750mg

naproxen (generic Naprosyn)

suspension: 125mg/5ml tablet: 250, 375, 500mg

naproxen sodium (generic Anaprox)

tablet: 275, 550mg

piroxicam (generic Feldene)

capsule: 10, 20mg

salsalate (generic Disalcid)

tablet: 500, 750mg

sulindac (generic Clinoril)

tablet: 150, 200mg

XI. NUTRITIONAL SUPPLEMENTS

MINERALS AND ELECTROLYTES

calcium acetate (Phoslo) capsule, tablet: 667mg

calcium carbonate (generic OsCal, TUMS)
OTC

tablet: 500mg

ferrous gluconate (generic Fergon) OTC, AL tablet: 330mg (age<50 Female, 21 Male)

ferrous sulfate (generic Feosol) OTC, AL tablet: 325mg (age<50 Female, <21 Male)

pediatric electrolytes (generic Pedialyte) OTC, AL

liquid: (age limit <21)

potassium chloride (generic K-Tab)

CR capsule: 10mEq CR tablet: 8mEq powder: 20mEq solution 10%, 20%

potassium chloride particles (generic K-Dur)

tablet: 10mEq, 20mEq

VITAMINS

calcitriol (Rocaltrol)

capsule: 0.25mcg, 0.5mcg

ergocalciferol (generic Drisdol)

capsule: 50,000U

folic acid (generic Folvite)

tablet: 1mg

multi-vitamins (generic One-A-Day) OTC, AL all generic multivitamins are covered (age limit <21)

multi-vitamins w/Iron (generic One-A-Day w/ Fe) OTC, AL

all generic multivitamins with iron are covered (age limit <21)

XI. NUTRITIONAL SUPPLEMENTS cont'd

VITAMINS cont'd

multi-vitamins w/minerals (generic Theragran-M) OTC, AL all generic multi-vitamins with minerals are covered (age<21)

ped vitamins ADC/FL (generic Tri-Vi-Flor)

chewable tab: 1mg

solution: 0.25mg/ml, 0.5mg/ml

ped vitamins ADC/FL-FE (generic Tri-Vi-Flor

w/Fe)

solution: 0.25mg/10mg/ml

ped. multiple vitamins/FL (generic Poly-Vi-

Flor)

chewable tab: 0.25, 0.5, 1mg drop: 0.25mg/ml, 0.5mg/ml

ped. multiple vitamins/FL-FE (generic Poly-Vi-

Flor w/Fe)

chewable tab: 0.5, 1mg drop: 0.25mg/ml, 0.5mg/ml

phytonodione (Mephyton)

tablet: 5mg

prenatal vitamins with FA (generic Materna)

AL

all generic prenatal vitamins are covered (age limit <50, Female only)

pyridoxine (Vitamin B6) OTC

tablet: 50,100, 250mg

sodium flouride (generic Luride)

chewable tab: 0.25mg

tablet: 5mg

vitamin B complex (Nephrocaps)

capsule: B Complex with C & Folic Acid

XII. OPHTHALMIC & OTIC AGENTS

ANALGESICS

benzocaine/antipyrine (generic Auralgan)

solution: 1.4%/5.5% OTIC

ANTI-INFECTIVES

acetic acid (generic VoSol)

solution: 2% OTIC

acetic acid/HC (VoSol - HC)

solution: 2%/1% OTIC

bacitracin (generic Baciguent)

ointment: 500U/gm OPHTH

bacitracin/neomycin/polymyxin B (Neosporin)

ointment: 400U/35mg/10,000U/gm

chloramphenicol (Chloroptic)

solution: 0.5%

ointment: 1% OPHTH

ciprofloxacin (generic Ciloxan)

solution: 0.3% OPHTH

ciprofloxacin/dexamethasone (Ciprodex)

solution: 0.3%/0.1% OTIC

dexamethasone/tobramycin (Tobradex)

ointment: 0.1%/0.3% OPHTH suspension: 0.1%/0.3% OPHTH

erythromycin (generic llotycin)

ointment: 5mg/gm OPHTH

gentamicin (generic Garamycin)

ointment, solution: 3mg/gm OPHTH

gramicidin/neomycin/polymyxin B (generic

Neosporin)

solution: 0.025mg/ml/1.75mg/ml/10,000U/

ml OPHTH

neomycin/polymyxin B/dexamethasone

(generic Maxitrol)

ointment, suspension: 0.35%/10,000U/0.1%

OPHTH

XII. OPHTHALMIC & OTIC AGENTS cont'd

ANTI-INFECTIVES cont'd

neomycin/polymyxin B/HC (generic

Cortisporin)

solution, suspension: 5mg/10,000U/1%

OTIC, OPHTH

ofloxacin (Floxin OTIC) QL=10ml

solution: .3% OTIC

polymyxin B/bacitracin (generic Polysporin)

ointment: 10,000U/500U/gm OPHTH

sulfacetamide (generic Bleph 10)

ointment, solution: 10% OPHTH

sulfacetamide/prednisolone (Blephamide)

ointment: 10%/0.2% OPHTH suspension: 10%/0.2% OPHTH

tobramycin (generic Tobrex)

solution: 0.3% OPHTH

tobramycin (Tobrex)

ointment: 0.3% OPHTH

triethanolamine oleate (Cerumenex)

solution: 10% OTIC

trifluridine (generic Viroptic)

solution 1% OPHTH

trimethoprim/polymyxin B (generic Polytrim)

solution: 0.1%/10,000U/ml OPHTH

vidarabine (Vira-A)

ointment: 3% OPHTH

ANTI-INFLAMMATORY & ALLERGY

azelastine (Optivar)

drop: 0.05% OPHTH

cromolyn sodium (generic Crolom)

solution: 4% OPHTH

dexamethasone (generic Decadron)

ointment: 0.05% OPHTH solution: 0.1% OPHTH

XII. OPHTHALMIC & OTIC AGENTS cont'd

ANTI-INFLAMMATORY & ALLERGY cont'd

dexamethasone/neomycin (generic

NeoDecadron)

solution: 0.1%/0.5% OPHTH

diclofenac (Voltaren)

solution: 0.1% OPHTH

fluorometholone (generic FML)

suspension: 0.1% OPHTH

flurbiprofen (generic Ocufen)

solution: 0.03% OPHTH

ketorolac (Acular)

solution: 0.5% OPHTH

Iodoxamine (Alomide)

solution 0.1% OPHTH

medrysone (generic HMS)

suspension: 1% OPHTH

naphazoline (generic Albalon)

solution: 0.1% OPHTH

neomycin/polymyxin/prednisolone (Polypred)

suspension: 0.5% OPHTH

prednisolone acetate (generic Pred Forte)

suspension: 1% OPHTH

prednisolone acetate (generic Pred Mild)

suspension: 0.12% OPHTH

prednisolone phosphate (generic Inflammase

Forte)

solution: 1% OPHTH

rimexolone (Vexol)

suspension: 1% OPHTH

CYCLOPLEGIC & MYDRIATIC

atropine (generic Isopto Atropine)

ointment: 0.5%, 1% OPHTH

solution: 1% OPHTH

XII. OPHTHALMIC & OTIC AGENTS cont'd

CYCLOPLEGIC & MYDRIATIC cont'd

cyclopentolate (generic Cyclogyl)

solution: 1% OPHTH

cyclopentolate (Cyclogyl)

solution: 0.5%, 2% OPHTH

homatropine (generic Isopto Homatropine)

solution: 5% OPHTH

homatropine (Isopto Homatropine)

solution: 2% OPHTH

phenylephrine (generic Neo-Synephrine)

solution: 2.5% OPHTH

tropicamide (generic Mydriacil)

solution: 0.5%, 1% OPHTH

GLAUCOMA

acetazolamide (generic Diamox)

tablet: 125, 250mg

apraclonidine (lopidine)

solution: 0.5%, 1% OPHTH

betaxolol (Betoptic-S)

suspension: 0.25% OPHTH

brimonidine tartrate (Alphagan-P)

solution: 0.15% OPHTH

brinzolamide (Azopt)

suspension: 1% OPHTH

carbachol (Isopto Carbachol)

solution: 0.75%, 1.5%, 2.25%, 3% OPHTH

demecarium bromide (Humorsol)

solution: 0.125%, 0.25% OPHTH

dipivefrin (generic Propine)

solution: 0.1% OPHTH

dorzolamide (Trusopt)

solution: 2% OPHTH

XII. OPHTHALMIC & OTIC AGENTS cont'd

GLAUCOMA cont'd

dorzolamide/timolol (Cosopt) solution 0.5% OPHTH

epinephrine (Epifrin) QL solution: 0.5%, 1% OPHTH

epinephrine (generic Epifrin) solution 2% OPHTH

epinephryl borate (Epinal) solution: 0.5%, 1% OPHTH

latanoprost (Xalatan) solution: 0.005% OPHTH

Ievobunolol (generic Betagan) solution: 0.5% OPHTH

methazolamide (generic Neptazane) tablet: 25, 50mg

pilocarpine (generic Pilocar)

solution: 0.5, 1, 2, 3, 4, 6% OPHTH

pilocarpine (Isopto Carpine) solution: 0.25%, 8%, 10% OPHTH

timolol hemihydrate (Betimol) solution: 0.25%, 0.5%

timolol maleate (generic Timoptic) solution:0.25%, 0.5% OPHTH

OCULAR LUBRICANTS

artificial tears (generic Tears Naturale) OTC solution or ointment

XIII. DERMATOLOGICALS

ACNE PRODUCTS

benzoyl peroxide (generic Benzac, generic Benzagel)

gel: 2.5, 5, 10% liquid: 5% lotion: 5,10%

XIII. DERMATOLOGICALS cont'd

ACNE PRODUCTS cont'd

clindamycin (generic Cleocin-T)

gel: 1%

lotion: 10mg/ml solution: 10mg/ml

erythromycin (generic Emgel)

gel: 2%

erythromycin (generic A/T/S, T-Stat)

solution: 1.5%

isotretinoin (Accutane) capsule: 10, 20, 40mg

metronidazole (Metrogel, generic Metrocream,

Metrolotion) cream: 0.75% gel: 0.75% lotion: 0.75%

tretinoin (generic Retin-A) cream: 0.025, 0.05, 0.1%

gel: 0.01%, 0.025%

ANTIBIOTICS - TOPICAL

bacitracin (generic Baciguent) OTC ointment:

bacitracin/polymyxin (generic polysporin) OTC ointment:

gentamicin sulfate (generic Garamycin)

cream: 0.1% ointment: 0.1%

mupirocin (generic Bactroban)

cream: 2% ointment: 2%

neomycin/polymyxin/bacitracin (generic

Neosporin) OTC ointment:

silver sulfadiazine (generic Silvadene)

cream: 10mg/gm

XIII. DERMATOLOGICALS cont'd

ANTIFUNGALS - TOPICAL

clotrimazole (generic Mycelex) OTC

cream: 1%

ketoconazole (generic Nizoral)

cream: 2% shampoo: 2%

miconazole (generic Monistat Derm) OTC

cream: 2%

nystatin (generic Mycostatin)

cream: 100,000U/gm ointment: 100,000U/gm

nystatin/triamcinolone (generic Mycolog)

cream: 100,000U/0.1%

tolnaftate (generic Tinactin) OTC

cream: 1% powder: 1%

ANTIPARASITICS

crotamiton (Eurax)

cream: 10% lotion: 10%

permethrin (NIX crème rinse) OTC

creme rinse: 1%

permethrin (generic Elimite)

cream: 5%

ANTIPSORIATICS

anthralin (generic Drithocreme HP)

cream: 1%

anthralin (Drithocreme)

cream: 0.1, 0.5%

calcipotriene (Dovonex) QL

cream: 0.005% (max=120gm per month) ointment: 0.005% (max=120gm per month) solution: 0.005% (max=60ml per month)

selenium sulfide (generic Selsun)

shampoo: 2.5%

XIII. DERMATOLOGICALS cont'd

ANTIVIRALS - TOPICAL

acyclovir (Zovirax) ointment: 5%

CORTICOSTEROIDS - HIGH POTENCY

betamethasone dipropionate (generic

Diprosone) cream: 0.05% lotion: 0.05% ointment: 0.05%

desoxymetasone (generic Topicort)

cream: 0.05%, 0.25%

gel: 0.05% ointment: 0.25%

fluocinonide (generic Lidex)

cream: 0.05% gel: 0.05% ointment: 0.05% solution: 0.05%

CORTICOSTEROIDS - LOW POTENCY

desonide (generic Tridesilon)

cream: 0.05% ointment: 0.05%

fluocinolone (generic Synalar)

cream: 0.01%, 0.025% ointment: 0.025% solution: 0.01%

hydrocortisone (generic CortAid) OTC

cream: 0.5, 1% ointment: 0.5, 1%

hydrocortisone (generic Hytone)

cream: 2.5% ointment: 2.5%

CORTICOSTEROIDS - MEDIUM POTENCY

betamethasone valerate (generic Valisone)

cream: 0.1% lotion: 0.1% ointment: 0.1%

XIII. DERMATOLOGICALS cont'd

CORTICOSTEROIDS - MEDIUM POTENCY cont'd

hydrocortisone valerate (generic Westcort)

cream: 0.2% ointment: 0.2%

mometasone furoate (generic Elocon)

cream: 0.1% lotion: 0.1% ointment: 0.1%

triamcinolone acetonide (generic Kenalog)

cream: 0.025%, 0.1%, 0.5%

lotion: 0.025%, 0.1%

ointment: 0.025%, 0.1%, 0.5%

CORTICOSTEROIDS - VERY HIGH POTENCY

betamethasone dipropionate augmented

(generic Diprolene) cream: 0.05% gel: 0.05% ointment: 0.05%

halobetasol propionate (generic Ultravate)

cream: 0.05% ointment: 0.05%

MISCELLANEOUS TOPICALS

ammonium lactate (generic Lac-Hydrin)

cream: 12%

ammonium lactate (generic Lac-Hydrin) OTC

lotion: 12%

calamine USP (generic Calamine) OTC, AL

lotion: (age limit <21)

capsaicin (generic Capsaicin) OTC

cream: 0.25, 0.75%

fluorouracil (Efudex)

cream: 5%

imiquimod (Aldara) QL

cream: 5% (max=1 kit per month)

XIII. DERMATOLOGICALS cont'd

MISCELLANEOUS TOPICALS cont'd

lidocaine gel

gel: 2%

pimecrolimus (Elidel) QL, ST

cream: 1% (max=60gm per month)

podofilox (generic Condylox)

solution: 0.5%

salacylic acid (generic Keralyt Gel)

gel: 6%

vitamin A&D (A&D Ointment) OTC, AL

ointment: (age limit <21)

zinc oxide (Zinc Oxide Ointment) OTC, AL

ointment: 20% (age limit <21)

XIV. SMOKING CESSATION PRODUCTS

bupropion hcl (generic Zyban) QL

ER tablet: 150mg (max=60 per 30 days x 3)

nicotine gum (Nicorette) OTC, PA, QL

gum: 2, 4mg

nicotine patch (Nicoderm CQ) OTC, QL

patch: 7, 14, 21mg (max=28 per 28 days x3)

nicotine transdermal system (generic

Habitrol) QL

patch: 7, 14, 21mg (max=28 per 28 days x3)

XV. MISCELLANEOUS PRODUCTS

Antialcoholic

disulfuram (Antabuse)

tablet: 250mg

naltrexone (generic Revia)

tablet: 50mg

XV. MISCELLANEOUS PRODUCTS cont'd

Mouth & Throat Products

chlorhexidine (generic Peridex) solution: 0.12%

Potassium Lowering Agents

sodium polystyrene sulfonate (generic

Kayexalate)

powder: 15gm/60ml suspension: 15gm/60ml

XV. MISCELLANEOUS PRODUCTS cont'd

Vasopressors

epinephrine (Epipen, Epipen Jr.) QL injection: 0.3mg, 0.15mg(Jr.)

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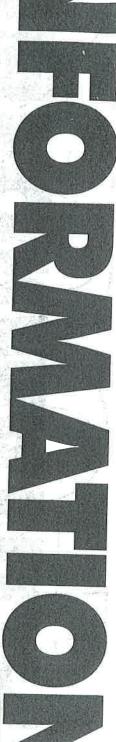
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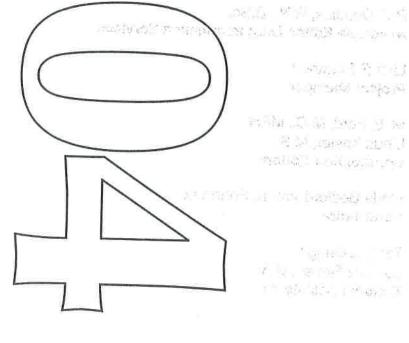
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American Society of Health-System Pharmacists®

Information on the pharmacokinetics of niacin is limited.

Niacin is rapidly and extensively (60-76% of dose) ab-Absorption sorbed following oral administration. Peak plasma concentrations of niacin following administration of an immediate-release (Niacor®) or extended-release (Niaspan®) niacin preparation generally are attained within 30-60 minutes or 4-5 hours after oral administration, respectively.

Peak plasma concentrations of niacin and metabolites following oral administration of Niaspan® extended-release tablets appear to be slightly higher in women than in men, possibly because of differences in metabolism. Limited data suggest that women may exhibit greater antilipemic response to niacin than men, possibly because of gender-specific differences in the metabolic rate or volume of distribution of the drug.

- Niacin is distributed mainly to the liver, kidney, and ad-■ Distribution ipose tissue. The drug also has been shown to distribute into milk in humans.
- Elimination Niacin is rapidly metabolized and undergoes extensive first-pass metabolism. The drug is converted to several metabolites, including nicotinuric acid (NUA), nicotinamide, and nicotinamide adenine dinucleotide (NAD). At doses used to treat hyperlipoproteinemia, the principal metabolic pathways appear to be saturable, and niacin is thought to exhibit nonlinear, dose-dependent pharmacokinetics. Nicotinamide does not appear to exert antilipemic effects; the activity of other metabolites on lipoprotein fractions currently are unknown. The plasma half-life of niacin has been reported to range from 20-60 minutes.

Niacin and its metabolites are rapidly excreted in urine. Following oral administration of single and multiple doses of an immediate-release (Niacor®) or extended-release (Niaspan®) niacin preparation, approximately 88 or 60-76% of the dose, respectively, was excreted in urine as unchanged drug and inactive metabolites.

Chemistry and Stability

- Chemistry Niacin (nicotinic acid) is an antilipemic agent. Niacin is commercially available as conventional (immediate-release) and extended-release preparations; the drug also is available in fixed combination with lovastatin. Niacin occurs as white crystals or crystalline powder with an acidic taste and is sparingly soluble in water, having an aqueous solubility of 16.7 mg/mL; the drug is freely soluble in boiling water and in boiling alcohol. Niacin has a pK_a of 4.85.
- Stability Niacin should be stored in well-closed, light-resistant containers at 20-25°C. When stored under these conditions, Niaspan® extendedrelease and Niacor® immediate-release tablets are stable for 3 and 2 years, respectively, after the date of manufacture.

Preparations

Niacin‡		
Oral		
Tablets	500 mg	Niacor® (scored), Upsher- Smith
Tablets, extended- release	500 mg	Niaspan*, Kos
	750 mg	Niaspan®, Kos
	1000 mg	Niaspan®, Kos
1.0		

‡For preparations used as dietary supplements, see the monograph on niacin in 88:08.

Lovastatin and Niacin

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Tablets

500 mg of extended-release Advicor*, Kos niacin and 20 mg of

lovastatin

750 mg of extended-release Advicor*, Kos niacin and 20 mg of

lovastatin

Advicor*, Kos

1 g of extended-release niacin and 20 mg of lovastatin

†Use is not currently included in the labeling approved by the US Food and Drug Administration Selected Revisions January 2003, © Copyright, September 1979, American Society of Health-System

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HYPOTENSIVE AGENTS

CENTRAL α -AGONISTS

Clonidine Clonidine Hydrochloride

Clonidine hydrochloride, an imidazoline-derivative hypotensive agent, is a selective α_2 -adrenergic agonist.

Uses

Clonidine hydrochloride and transdermal clonidine are ■ Hypertension used alone or in combination with other classes of antihypertensive agents in the management of hypertension. Thiazide diuretics are considered the preferred initial monotherapy for uncomplicated hypertension by the Joint National Committee (JNC 7) on the Prevention, Detection, Evaluation, and Treatment of Hypertension in the US. (See Uses: Hypertension, in the Thiazides General Statement 40:28.)

Although many hypertensive patients may be controlled by clonidine alone. the drug may be more effective when used with a diuretic. Clonidine hydrochloride has been used in conjunction with thiazide diuretics, chlorthalidone, or furosemide, producing a greater reduction in blood pressure than is obtained with either drug alone. Use of a diuretic may aid in overcoming tolerance to clonidine and permit reduction of clonidine dosage.

Clonidine may be useful in some patients who are unable to tolerate other adrenergic blocking agents because of severe postural hypotension. However, the possibility that geriatric patients may not tolerate the adverse cognitive effects of central α_2 -adrenergic agonists such as clonidine should be considered. Clonidine hydrochloride has been used with other hypotensive agents such as hydralazine, reserpine, or methyldopa, permitting a reduction in the dosage of each drug and, in some patients, minimizing adverse effects while maintaining blood pressure control. As when clonidine is used alone, satisfactory results are obtained in both supine and standing patients during combined drug therapy; marked fluctuations in blood pressure because of postural changes usually do not occur during combined therapy. As with other hypotensive agents, treatment with clonidine is not curative; upon withdrawal of the drug, blood pressure returns to pretreatment levels or greater. (See Cautions: Withdrawal Ef-

Transdermal clonidine has been effective in many patients for the management of mild to moderate hypertension when used alone or in combination with an oral thiazide diuretic and has also been successfully substituted for oral clonidine hydrochloride in some patients with mild to moderate hypertension whose therapy included the oral form of the drug. The role of transdermal clonidine relative to oral clonidine hydrochloride remains to be more fully evaluated; transdermal clonidine therapy may prove to be convenient in some patients (e.g., those in whom compliance with a daily dosing regimen may be a problem), but adverse dermatologic reactions may occur frequently.

For additional information on overall principles for treatment of hypertension and overall expert recommendations for such disease, see Uses: Hypertension in the Thiazides General Statement 40:28.

Hypertensive Crises Oral loading-dose regimens of clonidine hydrochloride† have been effective in rapidly reducing blood pressure in patients with severe hypertension in whom reduction of blood pressure was considered urgent, but not requiring emergency treatment. Hypertensive urgencies are those situations in which it is desirable to reduce blood pressure within a few hours. Such situations include the upper levels of severe hypertension, hypertension with optic disk edema, progressive target organ complications, and severe perioperative hypertension. Hypertensive urgencies can be managed with oral doses of drugs with a relatively rapid onset of action. Excessive falls in blood pressure should be avoided since they may precipitate renal, cerebral, or coronary ischemia.

Clonidine hydrochloride also has been used IV† in the management of acute hypertensive crisis† and in hypertensive episodes during labor†, as well as IM† or subcutaneously† in the management of late-onset toxemia of pregnancy†, with satisfactory results; however, an injectable dosage form is not currently available in the US. When the drug is administered IV, it must be injected very slowly in order to minimize the possible hypertension that may precede its hypotensive effect.

Clonidine hydrochloride administered by epidural infusion is used as adjunctive therapy in combination with opiates in the management of severe cancer pain that is not relieved by opiate analgesics alone. Epidural administration of analgesics should be considered only when maximum tolerated doses of opiate and adjunct analgesics administered by other routes (e.g., oral, transdermal, subcutaneous, IV) fail to relieve pain. (See Cautions: Precautions and Contraindications.) Consistent with the drug's mechanism of action, epidural

ed ere risses ınd ıral clonidine is more likely to be effective in patients with neuropathic pain rather than somatic or visceral pain.

In a double-blind, placebo-controlled, randomized study, cancer patients with severe intractable pain below the cervical dermatomes not controlled by oral, epidural, or IV opiate analgesics received epidural morphine with either clonidine hydrochloride 30 mcg/hour by continuous epidural infusion or placebo for 14 days. Pain relief, measured by a decrease in use of epidural morphine or a decrease in visual analog pain score, was reported in 45 or 21% of patients receiving epidural clonidine or placebo, respectively. In this study, substantial analgesic effects of clonidine appeared to be restricted to patients with neuropathic pain, characterized as localized, burning, shooting, or electriclike pain in a dermatomal or peripheral nerve distribution.

- Pheochromocytoma Clonidine is not indicated in patients with pheochromocytoma; however, unlike reserpine and guanethidine, it does not cause acute cardiovascular collapse in patients with this condition. Because of clonidine's ability to suppress plasma norepinephrine concentration in healthy individuals via stimulation of central α-adrenergic receptors, the drug has been used as an aid in the diagnosis of pheochromocytoma in hypertensive patients with suggestive symptoms and borderline catecholamine values; in patients with pheochromocytoma, plasma norepinephrine concentration is generally unchanged following administration of a single oral dose of clonidine, while patients with sympathetic hyperactivity exhibit a decrease in plasma norepinephrine concentration.
- Vascular Headaches Although clonidine has been used in the prophylaxis of migraine headaches†, the efficacy of the drug for this condition is questionable. Results of most studies using α-adrenergic agents (e.g., clonidine) for prevention of migraine headaches indicate that these drugs have limited or no efficacy in most patients, and therefore, some experts state that such use is not recommended. For further information on management and classification of migraine headache, see Vascular Headaches: General Principles in Migraine Therapy, under Uses in Sumatriptan 28.92.
- Dysmenorrhea Because clonidine reduces the responsiveness of blood vessels to vasodilators or vasoconstrictors, the drug has been used for the treatment of severe dysmenorrheat.
- Vasomotor Symptoms Associated with Menopause Clonidine has been used orally and transdermally for the management of vasomotor symptoms† (e.g., hot flashes) associated with menopause. Although limited data indicate that the drug may improve the severity and frequency of vasomotor symptoms in some patients, albeit modestly, the required dosages (exceeding the equivalent of 0.1 mg daily administered orally) may result in increased and, sometimes, intolerable adverse effects. Therefore, some clinicians recommend the use of clonidine for management of vasomotor symptoms mainly in postmenopausal women in whom estrogen replacement therapy is contraindicated or in those with preexisting hypertension.
- Opiate Dependence Clonidine hydrochloride has been used safely and effectively for rapid detoxification in the management of opiate withdrawal in opiate-dependent individuals, in both inpatient and outpatient settings. The exact role of clonidine and its efficacy compared with other methods of detoxification (e.g., methadone) remain to be clearly determined. Clonidine appears to be most useful as a transitional treatment between opiate dependence and administration of the opiate antagonist naltrexone. Clonidine also may be especially useful when detoxification using methadone is inappropriate, unsuccessful, or unavailable.
- Alcohol Dependence Clonidine also has been used in conjunction with benzodiazepines for the management of alcohol withdrawal†. Clonidine appears to be effective in reducing symptoms of the hyperadrenergic state associated with alcohol withdrawal, including elevated blood pressure, increased heart rate, tremor, sweating, and anxiety. However, clonidine has not been shown to prevent delirium or seizures, and the drug should be used only as an adjunct to benzodiazepines (not as monotherapy) for the treatment of alcohol withdrawal (see Uses: Alcohol Withdrawal in the Benzodiazepines General Statement 28:24.08). Some clinicians state that the use of clonidine may be particularly helpful in patients with certain coexisting conditions (e.g., opiate withdrawal).
- Smoking Cessation Clonidine is used for the management of nicotine (tobacco) dependence†. Nicotine dependence is a chronic relapsing disorder that requires ongoing assessment and often repeated intervention. Because effective nicotine dependence therapies are available, every patient should be offered effective treatment, and those who are unwilling to attempt cessation should be provided at least brief interventions designed to increase their motivation to stop tobacco use. The US Public Health Service (USPHS) currently recommends clonidine as a second-line drug for use under the supervision of a clinician. This recommendation is based on evidence from several clinical studies on smoking cessation showing that oral or transdermal clonidine therapy approximately doubles the abstinence rate relative to placebo. Second-line pharmacotherapy (e.g., clonidine, nortriptyline, combined therapy with 2 forms of nicotine replacement) is of a more limited role than first-line pharmacotherapy (i.e., bupropion [as extended-release tablets], nicotine polacrilex gum, transdermal nicotine, nicotine nasal spray, nicotine nasal inhaler) in part beach case 2:11-cv-00236-JPS Filed 10/29/13

cause of more concerns about potential adverse effects with second-line drugs than with first-line drugs. The use of second-line pharmacotherapy should be considered after first-line pharmacotherapy was attempted or considered and should be individualized based on patient considerations. Use of second-line pharmacotherapy for smoking cessation should be considered for patients who received first-line drugs but were not able to quit smoking or in whom these drugs are contraindicated. (See Guidelines under Uses: Smoking Cessation, in Nicotine 12:92.)

- Clonidine hydrochloride has been used topically† to reduce ■ Glaucoma intraocular pressure in the treatment of open-angle† (chronic simple) and secondary glaucoma† and hemorrhagic glaucoma associated with hypertension†.
- Attention Deficit Hyperactivity Disorder Clonidine has been used for the treatment of attention deficit hyperactivity disorder† (ADHD). Although pooled data from a retrospective analysis of studies in children with ADHD (with and without comorbid conditions [e.g., developmental delay, conduct or tic disorders]) indicate that the drug has produced a moderate reduction in symptoms of ADHD, stimulants (e.g., methylphenidate, amphetamines) remain the drugs of choice for the management of ADHD because of their greater efficacy compared with that of other drugs (e.g., clonidine). Clonidine generally has been shown to be more effective than placebo in the treatment of core symptoms of ADHD, but the magnitude of its effects is lower than with stimulants and efficacy has been established mainly in children with ADHD and comorbid conditions, especially sleep disturbances. However, because clonidine may improve motor tics in patients with Tourette's syndrome, some experts recommend its use as an adjunct to stimulant therapy in pediatric patients with ADHD whose comorbid tic disorder is not controlled by therapy with a stimulant alone. In pediatric patients without such comorbid psychiatric disorders, use of clonidine for the treatment of ADHD usually is not recommended, because of the current lack of evidence establishing safety and efficacy. For a more detailed discussion on the management of ADHD, see Uses: Attention Deficit Hyperactivity Disorder, in Methylphenidate 28:20.
- Other Uses Because of its GI effects (see Pharmacology: Other Effects), clonidine hydrochloride has been used with some success in a limited number of patients for the management of diarrhea† of various etiologies (e.g., narcotic bowel syndrome, idiopathic diarrhea associated with diabetes).

Dosage and Administration

Administration Clonidine hydrochloride is administered orally or by epidural infusion, and clonidine is administered percutaneously by topical application of a transdermal system. To ensure overnight blood pressure control with oral administration, the last dose of the day should be administered immediately before retiring. If oral clonidine therapy is to be discontinued, dosage of the drug should be slowly reduced over a period of 2-4 days to avoid the possibility of precipitating the withdrawal syndrome. (See Cautions: Withdrawal Effects.)

Patients receiving transdermal clonidine therapy should be carefully instructed in the use of the transdermal system. To obtain optimum results, patients should also be given a copy of the patient instructions provided by the manufacturer. To expose the adhesive surface of the system, the clear plastic protective strip should be peeled and discarded prior to administration. The transdermal system is applied topically to a dry, hairless area of intact skin on the upper arm or chest by firmly pressing the system with the adhesive side touching the skin. If the system becomes loose during the period of use, an adhesive overlay should be applied directly over the system to ensure good adhesion. If the patient develops localized skin irritation before completion of the intended period of use, the system may be removed and replaced with another system at a different application site. To minimize and/or prevent potential skin irritation, each transdermal system should be applied at a different site (e.g., systems may be applied progressively across the arms and chest in one direction or the other).

Specialized techniques are required for continuous epidural administration of clonidine hydrochloride; the drug should be administered via this route only by qualified individuals familiar with the techniques of administration and patient management problems associated with this route of clonidine administration. Prior to the implantation of a permanent controlled infusion device, screening should be conducted to ensure adequate response to epidural therapy. Chronic epidural analgesia should only be used when adequate pain relief cannot be achieved with less invasive therapies.

The injection for epidural use concentrate containing 500 mcg/mL must be diluted prior to use in sodium chloride 0.9% injection to provide a final concentration of 100 mcg/mL.

For continuous epidural infusion of clonidine hydrochloride, a controlledinfusion device is used to administer the drug. Infusion of clonidine into the upper thoracic spinal segments may be associated with substantial decreases in blood pressure. (See Cautions: Cardiovascular Effects.) The manufacturer states that administration of epidural clonidine above the C4 dermatome is contraindicated because of inadequate safety data supporting such use. Careful monitoring of infusion pump function and inspection of catheter tubing for obstruction or dislodgement is recommended to reduce the risk of inadvertent abrupt withdrawal of epidural clonidine infusion. Clonidine hydrochloride in-B Page 349 Februa 1649

jection for epidural infusion contains no preservatives, and partially used vials of the drug should be discarded,

To avoid the possibility of precipitating the withdrawal syndrome, clonidine therapy should not be discontinued abruptly. (See Cautions: Withdrawal Effects.)

Hypertension Dosage of clonidine and clonidine hydrochloride must be adjusted according to the patient's blood pressure response and tolerance. Adverse effects such as drowsiness and dry mouth may be minimized by increasing dosage gradually and/or by taking the larger portion of the daily dose at bedtime.

Tolerance to the hypotensive effect of clonidine or clonidine hydrochloride may develop in some patients, necessitating increased dosage or concomitant administration of a diuretic to enhance the hypotensive response to the drug.

Oral Dosage. For the management of hypertension, the usual initial adult oral dosage of clonidine hydrochloride is 0.05-0.1 mg twice daily; geriatric patients may benefit from the lower initial dosages. Most clinicians have reported satisfactory results with administration of the drug in 2 or 3 divided doses daily. Dosage may be increased by 0.1-0.2 mg daily or every few days or longer until the desired response is achieved. When clonidine hydrochloride is used alone, the usual oral maintenance dosage ranges from 0.05-0.4 mg twice daily. The manufacturers report 2.4 mg daily to be the maximum effective

When combination therapy is required, the commercially available preparations containing clonidine hydrochloride in fixed combination with chlorthalidone should not be used initially. Dosage should first be adjusted by administering each drug separately. If it is determined that the optimum maintenance dosage corresponds to the ratio in a commercial combination preparation, the fixed combination may be used. However, whenever dosage adjustment is necessary, each drug should be administered separately. Smaller than usual dosages of clonidine hydrochloride may be adequate in patients who are also receiving diuretics or other hypotensive drugs.

Clinical experience with the use of clonidine for the management of hypertension in children is currently lacking, and pediatric oral dosage has not been established.

Transdermal Dosage. When transdermal clonidine therapy is used for the management of hypertension, transdermal therapy is initiated in all adults with one system delivering 0.1 mg/24 hours applied once every 7 days. Because of interpatient variability in transdermal absorption, it is recommended that this initial dosage be used in all patients, including those who had been receiving oral clonidine hydrochloride therapy, and that dosage subsequently be titrated according to individual requirements; the relationship between the effective dosage of oral clonidine hydrochloride and that of transdermal clonidine is not predictable

If the desired reduction in blood pressure is not achieved after 1 or 2 weeks with the initial dosage, dosage may be increased by using 2 systems delivering 0.1 mg/24 hours or a larger dosage system. Subsequent dosage adjustments may be made at weekly intervals. The usual dosage range for transdermal clonidine recommended by some experts (e.g., JNC 7) is 0.1–0.3 mg/24 hours applied once every 7 days. Transdermal dosages exceeding 0.6 mg/24 hours (2 systems each delivering 0.3 mg/24 hours) are usually not associated with additional efficacy. In patients who develop localized skin irritation during the intended period of use (7 days), it may be necessary to move the transdermal system to a different site or replace it with another system at shorter intervals (e.g., every 3-5 days). Replacement of the transdermal system following a duration of less than 7 days may be required rarely to maintain blood pressure control

When transdermal therapy is initiated in patients who have been receiving low dosages of oral clonidine hydrochloride, some clinicians recommend continuing the usual oral dosage the first day the initial transdermal system is applied. When transdermal clonidine therapy is administered to patients already receiving other hypotensive agents, dosage of the other hypotensive agents should be gradually reduced when transdermal therapy is initiated since the hypotensive effect of transdermal clonidine may not begin until 2-3 days after application of the initial system; the other hypotensive agents may have to be continued, particularly in patients with more severe hypertension.

Blood Pressure Monitoring and Treatment Goals. Careful monitoring of blood pressure during initial titration or subsequent upward adjustment in dosage of clonidine hydrochloride is recommended. Large or abrupt reductions in blood pressure generally should be avoided.

Once antihypertensive drug therapy has been initiated, dosage generally is adjusted at approximately monthly intervals (more aggressively in high-risk patients [stage 2 hypertension, comorbid conditions]) if blood pressure control is inadequate at a given dosage; it may take months to control hypertension adequately while avoiding adverse effects of therapy. (For definition of stages of hypertension, see Initial Drug Therapy under Uses: Hypertension, in the Thiazides General Statement 40:28.) Once blood pressure has been stabilized, follow-up visits with the clinician generally can be scheduled at 3- to 6-month intervals, depending on patient status.

Because systolic blood pressure has been shown to be a more precise indicator of cardiovascular risk than diastolic blood pressure (except in patients younger than 50 years of age), the coordinating committee of the National High blood pressure as the principal clinical end point for detecting, evaluating, and treating hypertension, especially in middle-aged and geriatric patients. In addition, once the goal systolic blood pressure is attained, most hypertensive patients also will achieve the goal diastolic blood pressure.

The goal of hypertension management and prevention is to achieve and maintain a lifelong systolic blood pressure less than 140 mm Hg and a diastolic blood pressure less than 90 mm Hg if tolerated. Because treatment to lower levels may be particularly useful to prevent stroke, to preserve renal function, and to prevent or slow heart failure progression in hypertensive patients with diabetes mellitus or renal impairment, the goal of hypertension management and prevention in such patients is to achieve and maintain a systolic blood pressure less than 130 mm Hg and a diastolic blood pressure less than 80 mm Hg. Many experts recommend a goal of achieving and maintaining a systolic blood pressure of 125 mm Hg or less and a diastolic blood pressure of 75 mm Hg or less in hypertension management in patients with proteinuria (urinary protein excretion exceeding 1 g per 24 hours) and renal insufficiency (regardless of etiology).

For additional information on initiating and adjusting clonidine hydrochloride dosage in the management of hypertension, see Blood Pressure Monitoring and Treatment Goals under Dosage: Hypertension, in Dosage and Administration in the Thiazides General Statement 40:28.

Hypertensive Crises For the management of hypertensive crisist, clonidine hydrochloride in sodium chloride injection has been administered by IV injection† (currently not commercially available in the US) over a period of 5 minutes at a dose of 0.15-0.3 mg. If IV clonidine is used in the management of a hypertensive emergency, the initial goal of such therapy is to reduce mean arterial blood pressure by no more than 25% within minutes to 1 hour, followed by further reduction if stable toward 160/100 to 110 mm Hg within the next 2-6 hours, avoiding excessive declines in pressure that could precipitate renal, cerebral, or coronary ischemia. If this blood pressure is well tolerated and the patient is clinically stable, further gradual reductions toward normal can be implemented in the next 24-48 hours. Patients with aortic dissection should have their systolic pressure reduced to less than 100 mm Hg if tolerated.

For rapid reduction of blood pressure in patients with severe hypertension[†] in whom reduction of blood pressure was considered urgent but not requiring emergency treatment, clonidine hydrochloride has been administered orally in an initial dose of 0.1-0.2 mg, followed by hourly doses of 0.05-0.2 mg until a total dose of 0.5-0.7 mg had been given or diastolic blood pressure was controlled. Excessive falls in blood pressure should be avoided since they may precipitate renal, cerebral, or coronary ischemia. Thereafter, maintenance dosage of clonidine was adjusted according to the patient's response and tolerance.

Adult Dosage. When used for the relief of severe, intractable cancer pain that is unresponsive to epidural or spinal opiate analgesia or other more conventional methods of analgesia, the recommended initial dosage of clonidine hydrochloride in adults is 30 meg/hour, administered by continuous epidural infusion. The dosage may be adjusted based on clinical response and tolerance; however, clinical experience with infusion rates exceeding 40 mcg/ hour is limited. Patients should be closely monitored, particularly during the first few days of epidural clonidine therapy.

Pediatric Dosage. The recommended initial dosage of epidural clonidine hydrochloride in pediatric patients is 0.5 mcg/kg of body weight per hour. The dosage of epidural clonidine in pediatric patients should be cautiously adjusted based on clinical response.

Pheochromocytoma As an aid in the diagnosis of pheochromocytomat, clonidine hydrochloride has been administered orally as a single 0.3mg dose. To conduct the test, patients should rest in the supine position for 30 minutes, after which time, 2 blood samples for baseline determination of catecholamine concentrations are drawn at 5-minute intervals. The 0.3-mg dose is then administered and blood samples for catecholamine determinations are drawn at hourly intervals for 3 hours. In patients with pheochromocytoma, plasma norepinephrine concentrations generally remain unchanged following administration of clonidine, whereas plasma norepinephrine concentrations generally decrease in patients without pheochromocytoma.

Vascular Headache The oral dosage of clonidine hydrochloride used in the prophylaxis of migraine† is 0.025 mg 2-4 times a day or up to 0.15 mg daily in divided doses.

Dysmenorrhea For the treatment of dysmenorrheat, 0.025 mg of clonidine hydrochloride has been administered orally twice daily for 14 days before and during menses.

Vasomotor Symptoms Associated with Menopause Oral Dosage. Oral clonidine hydrochloride dosages of 0.025-0.2 mg twice daily have been employed in the management of vasomotor symptoms (e.g., hot flashes) associated with menopauset.

Transdermal Dosage. While comparative efficacy of various transdermal clonidine dosages have not been established, patients in clinical studies have received one transdermal system delivering 0.1 mg/24 hours applied once every 7 days

Opiate Dependence For rapid detoxification in the management of opiate withdrawal in opiate-dependent individuals†, various dosage regimens Blood Pressure Education 1 Program (1942 36) 1 Program property of the Carefully in1650 AHFS DRUG INFORMATION® 2004

dividualized according to the patient's response and tolerance, and patients must be closely monitored and supervised. Because of varying sensitivity to clonidine's sedative, hypotensive, and withdrawal-suppressing effects, it may be difficult or impossible to establish a dosage regimen that adequately suppresses withdrawal without producing intolerable adverse effects. Some clinicians administer an initial oral test dose of clonidine hydrochloride of 0.005 or 0.006 mg/kg; if signs and symptoms of withdrawal are suppressed, patients then receive an oral dosage of 0.017 mg/kg daily, given in 3 or 4 divided doses, generally for about 10 days. Alternatively, some clinicians have administered an initial oral dosage of 0.1 mg 3 or 4 times daily, with dosage adjusted by 0.1–0.2 mg per day according to the patient's response and tolerance. Dosage usually ranges from 0.3–1.2 mg daily. When clonidine hydrochloride therapy is discontinued, dosage has been reduced by 0.1–0.2 mg daily. Clinicians should consult published protocols for more specific information.

Alcohol Dependence While dosages of clonidine hydrochloride in the management of alcohol dependence† have not been established, oral dosages of 0.5 mg twice or 3 times daily have been shown to reduce tremor, heart rate, and blood pressure in patients with alcohol withdrawal.

Smoking Cessation Optimum dosage of oral clonidine hydrochloride or transdermal clonidine for smoking cessation† (nicotine [tobacco] dependence) has not been established, and various regimens have been employed.

Oral Dosage. For use in the cessation of smoking†, the initial adult oral dosage of clonidine hydrochloride is typically 0.1 mg twice daily. Therapy with the drug is initiated on the day set as the date of cessation of smoking or shortly before this date (e.g., up to 3 days prior). Dosage may be increased each week by 0.1 mg daily, if needed. In clinical studies, oral dosages varied from 0.15–0.75 mg daily, without a clear relationship to achievement of cessation of smoking. The duration of oral therapy with clonidine hydrochloride also varied in these studies, ranging from 3–10 weeks.

Transdermal Dosage. When transdermal clonidine is used for the cessation of smoking†, therapy is initiated typically in adults with one system delivering 0.1 mg/24 hours applied once every 7 days. Therapy with the drug is initiated on the day set as the date of cessation of smoking or shortly before this date (e.g., up to 3 days prior). Dosage may be increased at weekly intervals by 0.1 mg/24 hours, if needed. In clinical studies, the transdermal dosage varied from 0.1–0.2 mg/24 hours, without a clear relationship to achievement of cessation of smoking. The duration of transdermal clonidine therapy also varied in these studies, ranging from 3–10 weeks.

Glaucoma In the treatment of glaucoma[†], clonidine hydrochloride has been applied topically[†] in the form of 0.125%, 0.25%, or 0.5% ophthalmic solutions or as a 0.1% ophthalmic ointment. The 0.25% solution appears to provide maximum effectiveness with minimum adverse effects.

Attention Deficit Hyperactivity Disorder For the management of attention deficit hyperactivity disorder (ADHD)†, the initial oral daily dosage of clonidine hydrochloride in pediatric patients is 0.05 mg given as a single dose at bedtime. Thereafter, dosages may be cautiously increased over a period of 2-4 weeks, in order to minimize development of adverse effects (e.g., sedation). Maintenance dosages of clonidine hydrochloride range from 0.05-0.4 mg daily (depending on tolerance and patient's weight). Usually, pediatric patients may receive the maximum tolerated dosages of clonidine hydrochloride for 2-8 weeks in order to assess treatment response, although it should be considered that onset of action of clonidine may be more variable than that associated with stimulants or antidepressants. The American Heart Association (AHA) states that ECG monitoring is not required in pediatric patients receiving clonidine for ADHD; however, several experts recommend weekly office visits during clonidine titration period to monitor both erect and supine blood pressure and heart rate.

Dosage in Renal Impairment

Smaller than usual dosages of clonidine hydrochloride may be adequate in patients with renal impairment. Dosage should be adjusted according to the degree of renal impairment. Some clinicians suggest that adjustment of clonidine hydrochloride dosage is not necessary in patients with creatinine clearances of 10 mL/minute or greater, but those with lower clearances can receive 50–75% of the usual dosage. Supplemental doses after hemodialysis are not necessary.

Cautions

Adverse effects occurring most frequently during oral clonidine hydrochloride therapy are dry mouth, drowsiness and sedation, and constipation. Dizziness, headache, fatigue, and weakness have also been reported. Generally, these adverse effects tend to diminish with continued therapy or may be relieved by a reduction in dosage. Adverse effects occurring with transdermal clonidine generally appear to be similar to those occurring with oral therapy; however, systemic adverse effects with transdermal clonidine appear to be less severe and possibly may occur less frequently than with oral therapy. Most adverse systemic effects occurring during transdermal therapy have been mild and have tended to diminish with continued treatment. The most frequently occurring adverse effects during transdermal therapy have been dry mouth, drowsiness, and local adverse dermatologic effects. Adverse effects reported most frequently in patients with cancer receiving clonidine by epidural infusion in com-

bination with epidural morphine in a controlled clinical trial included hypotension, postural hypotension, and dry mouth, which occurred in 45, 32, and 16% of patients, respectively.

- Nervous System Effects Drowsiness has been reported in about 35, 13, or 12% of patients receiving oral, epidural, or transdermal clonidine, respectively. In addition to drowsiness, sedation, dizziness, headache, fatigue, and weakness, other adverse nervous system effects of clonidine include lethargy, vivid dreams, nightmares, insomnia, behavioral changes, nervousness, restlessness, anxiety, mental depression, visual and auditory hallucinations, and delirium. Cerebrovascular accidents also have been reported rarely in patients receiving epidural clonidine. Depression, which occurs often in patients with cancer, may be exacerbated by the use of epidural clonidine. Therefore, the manufacturer recommends that patients be monitored for signs and symptoms of depression (especially those with a history of affective disorders). Sedation and ventilatory abnormalities, usually mild, have been reported in patients receiving bolus epidural doses of clonidine that were substantially higher than the infusion rate recommended for the treatment of cancer pain. Tolerance to these effects may occur with chronic administration of the drug.
- patients receiving oral, transdermal, or epidural clonidine, respectively. Nausea and vomiting have occurred in about 5% of patients and anorexia and malaise in about 1% of patients receiving oral clonidine. Nausea and vomiting were reported in about 13 and 11%, respectively, of patients receiving clonidine by epidural infusion in combination with epidural morphine for the treatment of intractable cancer pain in a controlled clinical trial. Parotid pain has occurred rarely. Constipation, nausea, dry throat, and change in taste have been reported in patients receiving transdermal clonidine.
- Cardiovascular Effects Orthostatic symptoms have occurred in about 3% of patients receiving oral clonidine; palpitation and tachycardia, and bradycardia have occurred in about 0.5% of patients receiving oral drug. Rare cases of sinus bradycardia and atrioventricular block, with and without concomitant cardiac glycoside therapy, have been reported. Congestive heart failure, Raynaud's phenomenon, flushes, facial pallor, and ECG abnormalities (e.g., arrhythmias, conduction disturbances such as AV block) have also been reported.

Hypotension occurred in about 45% of patients receiving clonidine by epidural infusion as adjunctive therapy with epidural morphine for the treatment of cancer pain. In a 14-day clinical trial, hypotension usually was reported within the first 4 days of epidural clonidine therapy; however, hypotension also occurred throughout the duration of the study. Hypotension, which can be severe, usually responds to treatment with IV fluids and, if necessary, parenteral ephedrine. Hypotension appears to occur more frequently in women, in patients with a lower body weight, and in patients with higher serum clonidine concentrations.

Decreased heart rate has been reported frequently in patients receiving epidural clonidine, while AV block greater than first degree in severity has been reported rarely. Atropine may be used to treat symptomatic bradycardia when necessary. Increases in heart rate associated with hypovolemia may be masked by clonidine therapy.

- Metabolic and Endocrine Effects Some patients gain weight during the first few days of oral clonidine therapy because of sodium and fluid retention. Sodium retention usually lasts only 3 or 4 days and may be avoided or relieved by administration of a diuretic. Gynecomastia has occurred in about 0.1% of patients receiving oral clonidine. Transient elevation of blood glucose concentration after single large doses of clonidine hydrochloride has been reported; however, no effects on glucose metabolism have been reported during long-term use of the drug, and diabetic patients have remained in control while taking clonidine hydrochloride. Rarely, transient elevation of serum creatine kinase (CK, creatine phosphokinase, CPK) concentrations have been associated with use of the drug.
- **Dermatologic Effects** Rash has occurred in about 1% of patients; pruritus in about 0.7% of patients; hives, angioedema, and urticaria in about 0.5% of patients; and alopecia in about 0.2% of patients receiving oral clonidine.

In clinical studies, transient localized skin reactions have occurred in 15-50% of patients receiving transdermal clonidine therapy. Localized skin reactions consist principally of pruritus, but erythema may also occur; erythema and pruritus occur more commonly in patients who use an adhesive overlay over the transdermal system for the entire 7-day application period. Localized skin reactions are usually readily reversible following removal of the transdermal system and have usually not required discontinuance of transdermal therapy. Allergic contact sensitization to clonidine has occurred in about 20% of patients with transdermal therapy, most frequently in white females and least frequently in black males; the dermatitis may require discontinuance of transdermal therapy. Although systemic anaphylactic reactions have not been reported to date, subsequent administration of oral clonidine to patients who experience allergic reactions with transdermal therapy may result in a recurrence of the reaction or development of a generalized rash. (See Cautions: Precautions and Contraindications.) Localized vesiculation, hyperpigmentation (at the application site), edema, excoriation, burning, throbbing, blanching, papules, and generalized macular rash have also occurred in patients receiving transdermal clonidine. Maculopapular rash, urticaria, and angioedema involving the face (and the tongue in one case) have also been reported, but a causal relationship was not established.

- Genitourinary Effects Decreased sexual activity, impotence, and loss of libido have occurred in about 3% of patients receiving oral clonidine; impotence or sexual dysfunction have occurred rarely with transdermal therapy. Nocturia has occurred in about 1% of patients, difficulty in micturition in about 0.2% of patients, and urinary retention in about 0.1% of patients receiving oral clonidine.
- Hepatic Effects Mild, transient abnormalities in liver function test results have occurred during oral clonidine therapy. Hepatitis has been reported rarely; one case of hepatitis without icterus and hyperbilirubinemia occurred in a patient receiving clonidine hydrochloride, chlorthalidone, and papaverine, but a relationship to clonidine has not been established.
- Other Adverse Effects Muscle or joint pain has occurred in about 0.6% of patients and leg cramps in about 0.3% of patients receiving oral clonidine. Dryness of the nasal mucosa; blurred vision; dryness, itching, and burning of the eyes; weakly positive Coombs' test results; fever; and increased sensitivity to alcohol have also been reported in patients receiving oral clonidine.

In several studies in albino rats receiving oral clonidine hydrochloride for 6 months or longer, the drug produced a dose-dependent increase in the frequency and severity of spontaneous retinal degeneration. Distribution studies in dogs and monkeys showed that clonidine is concentrated in the choroid of the eye. Ophthalmologic examinations performed prior to and periodically during oral clonidine hydrochloride therapy in humans (for 24 months or longer in some) revealed no evidence of drug-induced ophthalmologic abnormalities, except dry eyes, nor was there evidence of altered retinal function as determined by specialized tests such as electroretinography and macular dazzle.

Implantable epidural catheters are associated with a risk of infection, including meningitis and/or epidural abscess. The incidence of catheter-related infections is about 5–20%, and depends on several factors, including the clinical status of the patient, type of catheter used, catheter placement technique, quality of catheter care, and duration of catheter placement. The possibility of catheter-related infection should be considered in patients receiving epidural clonidine who develop a fever.

withdrawal Effects Abrupt withdrawal of oral clonidine therapy may result in a rapid increase of systolic and diastolic blood pressures, with associated symptoms such as nervousness, agitation, restlessness, anxiety, insomnia, headache, sweating, palpitation, increased heart rate, tremor, hiccups, stomach pains, nausea, muscle pains, and increased salivation. The exact mechanism(s) of the withdrawal syndrome following discontinuance of α -adrenergic agonists has not been determined but may involve increased concentrations of circulating catecholamines, increased sensitivity of adrenergic receptors, enhanced renin-angiotensin system activity, decreased vagal function, failure of autoregulation of cerebral blood flow, and/or failure of central α_2 -adrenergic receptor mechanisms that regulate sympathetic outflow from the CNS and modulate baroreflex function.

The clonidine withdrawal syndrome is more pronounced after abrupt cessation of long-term therapy than after short-term (1-2 months) therapy and has usually been associated with previous administration of high oral dosages (greater than 1.2 mg daily) and/or with continuation of concomitant β-adrenergic blocking therapy. In addition, the risk of adverse effects following abrupt discontinuance of clonidine therapy may be increased in patients with a history of hypertension and/or other underlying cardiovascular conditions. (See Cautions: Precautions and Contraindications.) When the drug is discontinued abruptly, symptoms such as restlessness and headache may begin to appear 2-3 hours after a dose is missed and blood pressure may increase substantially within 8-24 hours. In a few patients, blood pressure exceeded pretreatment levels. Rare cases of hypertensive encephalopathy, cerebrovascular accidents, and death occurring after abrupt cessation of clonidine therapy have been reported. It has been postulated that the risk of precipitating the withdrawal syndrome should be reduced substantially with use of transdermal clonidine because of the pharmacodynamics associated with this dosage form; however, withdrawal symptoms have been reported occasionally following discontinuance of transdermal therapy or when absorption of the drug was impaired because of dermatologic changes (e.g., contact dermatitis) under the transdermal system. In one patient, withdrawal symptoms (severe rebound hypertension, tachycardia, headache, diaphoresis) appeared approximately 36-72 hours after discontinuance of transdermal therapy but responded to sublingual nifedipine and oral clonidine therapy. In a few geriatric patients, blood pressure has increased to levels exceeding baseline approximately 3-7 days after transdermal therapy was discontinued, although other signs of a hyperadrenergic state were

An excessive rise in blood pressure after oral clonidine withdrawal can be reversed and symptoms relieved by resumption of oral clonidine or by combined administration of α - and β -adrenergic blocking agents (e.g., phentolamine or prazosin with atenolol, labetalol, or propranolol). Rebound hypertension may present a particular problem if oral clonidine therapy must be interrupted for surgery. It has been reported that when the drug was discontin-

ued 8 hours or more prior to surgery, hypertension resulted during and after surgery; however, when clonidine was administered 4–6 hours preoperatively, only minor hypertension developed and hypotension requiring treatment did not occur.

In a controlled clinical trial in cancer patients receiving epidural clonidine as an adjunct to epidural morphine for the treatment of pain, about 10% of patients receiving 720 mcg of clonidine hydrochloride daily experienced rebound hypertension following abrupt discontinuance of the drug; one patient subsequently suffered a cerebrovascular accident. Rebound hypertension following discontinuance of epidural clonidine can be reversed by administration of clonidine or IV phentolamine. In patients who are receiving concomitant therapy with a β -adrenergic blocking agent, the β -blocker should be discontinual several days prior to discontinuance (by gradual tapering) of epidural clonidine.

■ Precautions and Contraindications When clonidine hydrochloride is used as a fixed-combination preparation that includes chlorthalidone, the cautions, precautions, and contraindications associated with thiazide diuretics must be considered in addition to those associated with clonidine.

Because of the risk of rebound hypertension, patients receiving clonidine preparations should be warned of the danger of missing doses or stopping the drug without consulting their physician. (See Cautions: Withdrawal Effects.) When discontinuing oral or epidural clonidine therapy, a rapid rise in blood pressure may be minimized or prevented by tapered withdrawal of the drug over 2-4 days. Tapered withdrawal of transdermal clonidine or initiation of a tapered regimen of oral clonidine also is recommended by some clinicians when the transdermal dosage form is discontinued, particularly in geriatric patients. If clonidine therapy is to be discontinued in patients receiving clonidine and a β -adrenergic blocking agent concomitantly, the β -adrenergic blocker should be discontinued several days before clonidine therapy is discontinued. It is recommended that clonidine therapy not be interrupted for surgery; transdermal therapy can be continued throughout the perioperative period and oral therapy should be continued to within 4 hours before surgery. Blood pressure should be carefully monitored during surgery and additional measures to control blood pressure should be available if necessary. If clonidine therapy must be interrupted for surgery, parenteral hypotensive therapy should be administered as necessary, and clonidine therapy should be resumed as soon as possible. If transdermal therapy is initiated during the perioperative period, it must be kept in mind that therapeutic plasma clonidine concentrations are not achieved until 2-3 days after initial application of the transdermal system.

Clonidine transdermal systems should be removed from the site(s) of application prior to attempting defibrillation or cardioversion since altered electrical conductivity and enhanced potential for electrical arcing may occur.

Patients receiving transdermal clonidine therapy should be advised that if the transdermal system begins to loosen from the skin after application, an adhesive overlay should be applied directly over the system to ensure good adhesion over the period of application. Patients receiving transdermal therapy who develop moderate or severe erythema and/or localized vesicle formation at the application site or who develop a generalized rash should consult their physician promptly about the need to remove the transdermal system. In patients who develop localized contact sensitization to clonidine with transdermal therapy, subsequent administration of oral clonidine hydrochloride may be associated with development of a generalized rash. In patients receiving transdermal therapy who develop an allergic reaction to clonidine that extends beyond the local application site (e.g., generalized rash, urticaria, angioedema), subsequent administration of oral clonidine hydrochloride may elicit a similar reaction. Patients receiving transdermal clonidine therapy should be cautioned that even after use, the transdermal system contains active medication that may be harmful if accidentally applied or ingested by infants or children. (See Acute Toxicity: Manifestations.) Patients should be instructed to handle the used transdermal system carefully (e.g., fold the system in half with the sticky sides together) and to dispose of the system out of the reach of children.

Epidural clonidine should be used only in patients with severe cancer pain that has failed to respond to an adequate trial with opiate analgesics. The drug is not recommended for the management of obstetric, postpartum, or perioperative pain. Careful monitoring of infusion pump function and inspection of catheter tubing for obstruction or dislodgement is recommended to reduce the risk of accidental abrupt withdrawal of epidural clonidine. Patients should be instructed to notify their clinician immediately in case of inadvertent interruption of epidural clonidine administration. Specialized techniques are required for continuous epidural administration of clonidine hydrochloride; the drug should be administered via this route only by qualified individuals familiar with the techniques of administration and patient management problems associated with this route of clonidine administration. Epidural drug administration is contraindicated in patients receiving anticoagulant therapy, in those with a bleeding diathesis, and in the presence of an injection site infection. Administration of epidural clonidine also is not recommended in most patients with severe cardiovascular disease or in patients who are hemodynamically unstable. The manufacturer states that administration of epidural clonidine above the C4 dermatome is contraindicated because of inadequate safety data supporting such use

Clonidine should be used with caution in patients with severe coronary insufficiency, recent myocardial infarction, cerebrovascular disease, chronic renal failure, Raynaud's disease, or thromboangiitis obliterans. Patients with a history of mental depression require careful supervision while receiving clon-

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idine as they may be subject to further depressive episodes. Patients who engage in potentially hazardous activities such as operating machinery or driving should be warned of the possible sedative effect of the drug.

The possibility that clonidine may lower blood pressure in patients receiving the drug for conditions other than hypertension (e.g., smoking cessation, pain management, attention deficit hyperactivity disorder) should be considered, and blood pressure should be monitored as appropriate. In addition, the possibility of rebound hypertension and other withdrawal effects should be considered when the drug is discontinued in such patients; abrupt discontinuance should be avoided.

A dose-dependent increase in the incidence and severity of spontaneously occurring retinal degeneration was observed in albino rats receiving the drug for 6 months or longer, especially those receiving strong exposure to light. Although serious adverse ophthalmologic effects have not been reported in patients receiving clonidine, periodic eye examinations should be performed in patients receiving the drug.

Clonidine is contraindicated in patients with known hypersensitivity to the drug or to any ingredient or component in the formulation.

- Safe use of oral clonidine hydrochloride for ■ Pediatric Precautions the management of hypertension and attention deficit hyperactivity disorder in children has not been established, but clinical studies are currently under way to determine pediatric safety and efficacy. Safety and efficacy of clonidine transdermal system in children younger than 12 years of age have not been established. The safety and efficacy of clonidine hydrochloride epidural infusion have been established in pediatric patients who are old enough to tolerate placement and management of an epidural catheter, based on evidence from adequate, well-controlled studies in adults and experience with the use of clonidine in pediatric patients for other indications. Epidural clonidine should be used only in pediatric patients with severe, intractable cancer pain that is unresponsive to epidural or spinal opiates and to other conventional analgesic therapy.
- Mutagenicity and Carcinogenicity There was no evidence of clonidine-induced mutagenesis in vitro in the Ames microbial mutagen test. There was no evidence of carcinogenic activity in rats following 132 weeks of oral clonidine hydrochloride at dosages 32-46 times the maximum recommended human oral dosage (equivalent to about 111-160 times the maximum recommended human transdermal dosage).

■ Pregnancy, Fertility, and Lactation

Pregnancy

Reproduction studies in rabbits using oral clonidine hydrochloride dosages up to 3 times the maximum recommended human dosage or transdermal clonidine dosages up to 10.5 times the maximum recommended human dosage have not revealed evidence of teratogenicity or embryotoxicity. However, in female rats receiving the drug continuously for 2 months prior to mating, an increased incidence of fetal resorptions occurred with oral dosages as low as one-third the maximum recommended human dosage or transdermal dosages as low as 1.2 times the maximum recommended human dosage; resorptions were not increased when these or higher dosages were administered during days 6-15 of gestation. There are no adequate and controlled studies to date using clonidine in pregnant women, and the drug should be used during pregnancy only when clearly needed.

Smoking cessation programs consisting of behavioral and educational rather than pharmacologic interventions should be tried in pregnant women before drug therapy is considered. Smoking cessation therapy with clonidine, which is a second-line agent, should be used during pregnancy only if the increased likelihood of smoking cessation, with its potential benefits, justifies the potential risk to the fetus and patient of clonidine and possible continued smoking, and first-line pharmacotherapy (e.g., bupropion, nicotine replacement) has failed. Although smoking cessation prior to conception or early in pregnancy is most beneficial, health benefits result from cessation at anytime; therefore, effective smoking cessation interventions should be offered at the first prenatal visit and persist throughout the course of pregnancy for women

who continue smoking after conception.

Reproduction studies in rats using oral clonidine hydrochloride dosages up to 0.15 mg/kg daily (about 3 or 10.5 times the maximum recommended human oral or transdermal dosage, respectively) have not revealed evidence of impaired fertility; however, fertility was impaired at oral dosages ranging from 0.5-2 mg/kg daily (about 10-40 or 35-140 times the maximum recommended human oral or transdermal dosage, respectively).

Lactation

Since clonidine is distributed into milk, the drug should be used with caution in nursing women. The manufacturer of parenteral clonidine states that because of the potential for serious adverse reactions to clonidine in nursing infants, a decision should be made whether to discontinue nursing or the drug, taking into account the importance of the drug to the woman.

Drug Interactions

CNS Depressants Clonidine may be additive with, or may potentiate the action of, other CNS depressants such as opiates or other analgesics, barbiturates or other sedatives, anesthetics, or alcohol. Concomitant administration of opiate analgesics with clonidine also may potentiate the hypotensive effects of clonidine.

■ Psychotherapeutic Agents Tricyclic antidepressants (i.e., imipramine, desipramine) have reportedly inhibited the hypotensive effect of clonidine. The increase in blood pressure usually occurs during the second week of tricyclic antidepressant therapy, but occasionally may occur during the first several days of concomitant therapy. The possibility of this interaction should be considered in patients receiving clonidine and tricyclic antidepressants concomitantly; blood pressure should be closely monitored during the first several weeks of concurrent therapy, and dosage of clonidine should be increased to adequately control hypertension if necessary. Alternatively, other hypotensive agents that do not interact with tricyclic antidepressants may be substituted, but clonidine therapy should not be discontinued abruptly. If tricyclic antidepressant therapy is discontinued in patients receiving clonidine, the hypotensive effect of clonidine may increase; blood pressure should be monitored and dosage of clonidine reduced if necessary. In rats, concurrent administration of clonidine and amitriptyline has produced corneal lesions within 5 days. The effects of tricyclic antidepressants on the analgesic effect of epidural clonidine hydrochloride are not known.

Clonidine withdrawal may result in an excess of circulating catecholamines; therefore, caution should be exercised in concomitant use of drugs which affect the metabolism or tissue uptake of these amines (monoamine oxidase inhibitors

or tricyclic antidepressants, respectively).

Acute delirium has been reported in at least one patient receiving fluphenazine concomitantly with oral clonidine. The symptoms resolved following discontinuance of clonidine and recurred upon rechallenge with the drug

■ Cardiovascular Drugs When clonidine is administered with other hypotensive agents, including diuretics, the hypotensive effect of clonidine may be increased. This effect is usually used to therapeutic advantage in antihypertensive therapy; however, careful adjustment of dosage is necessary when these drugs are used concomitantly.

Because clonidine may produce bradycardia, the possibility of additive effects should be considered if it is given concomitantly with other drugs that decrease the heart rate such as guanethidine, β -adrenergic blocking agents (e.g.,

propranolol), or cardiac glycosides.

Because β -adrenergic blocking agents may exacerbate rebound hypertension that may occur following discontinuance of clonidine therapy, β-adrenergic blocking agents should be discontinued several days before gradual withdrawal of clonidine when clonidine therapy is to be discontinued in patients receiving a β -adrenergic blocking agent and clonidine concurrently. If clonidine therapy is to be replaced by a β -adrenergic blocking agent, administration of the β -adrenergic blocking agent should be delayed for several days after clonidine therapy has been discontinued.

Other Drugs Epidural clonidine may prolong the duration of the pharmacologic effects, including both sensory and motor blockade, of epidural local anesthetics.

Acute Toxicity

- Pathogenesis The oral LD₅₀ of clonidine hydrochloride is 206 and 465 mg/kg in mice and rats, respectively.
- Manifestations Signs and symptoms of overdosage of clonidine include hypotension (which may be profound), transient hypertension, weakness, vomiting, irritability, diminished or absent reflexes, lethargy, somnolence, deep sedation or coma, skin pallor, hypothermia, decreased or irregular heart rate, cardiac conduction defects (e.g., high-grade atrioventricular block), dryness of the mouth, constricted pupils with poor reaction to light, apnea, respiratory depression, hypoventilation, and seizures. Signs and symptoms of clonidine overdosage usually occur within 30-60 minutes after ingestion and may persist for 36-48 hours. In one individual who reportedly ingested 100 mg of clonidine hydrochloride, plasma clonidine concentrations were 60, 90, 370, 120, and 120 ng/mL 1, 1.5, 2, 5.5, and 6.5 hours after ingestion. Signs and symptoms of overdosage in this patient included transient hypertension followed by hypotension, bradycardia, apnea, hallucinations, partial coma, and ventricular premature contractions; the patient recovered following intensive symptomatic and supportive treatment. In a 2-year old infant who apparently ingested clonidine from a used and discarded transdermal system, a serum clonidine concentration determined 24 hours after ingestion was approximately 8 ng/mL (therapeutic range: 0.5-4.5 ng/mL). In this infant, lethargy developed over several hours and was accompanied by bradycardia, hypotension, miosis, and gasping respirations; the patient was monitored in an intensive care unit and recovered over a period of 16 hours without specific treatment.
- m Treatment If signs and symptoms of clonidine overdosage occur in patients receiving transdermal therapy, all transdermal systems should be removed. In acute overdosage with oral clonidine, the stomach should be emptied immediately by inducing emesis or by lavage followed by administration of an activated charcoal slurry and a saline cathartic. Gastric lavage, rather than emesis, is preferred in patients who are sedate and drowsy since coma can develop rapidly. If the patient is comatose, having seizures, or lacks the gag reflex,

gastric lavage may be performed if an endotracheal tube with cuff inflated is in place to prevent aspiration of gastric contents. Supportive and symptomatic treatment should be initiated and an adequate airway established and maintained since respiratory depression or apnea may ensue. Hypotension can initially be managed with IV fluids and by placing the the patient in Trendelenburg's position. IV infusion of dopamine may be useful for severe, persistent hypotension. IV atropine sulfate may be useful for symptomatic bradycardia, The manufacturers state that IV administration of 10 mg of tolazoline at 30minute intervals may reverse the effects of clonidine overdosage if other measures fail; limited data from patients with hypertension indicate that tolazoline can reverse the cardiovascular effects (e.g., bradycardia, hypotension) of clonidine. Hypertension has been managed with IV furosemide or diazoxide or α adrenergic blocking agents (e.g., phentolamine). Additional information on the efficacy of α -adrenergic blockers in the treatment of clonidine overdosage is necessary. IV naloxone has been administered in several patients following clonidine overdosage, but often has had little, if any, effect in reversing signs and symptoms of intoxication; additional study on the potential benefit of naloxone therapy in the treatment of acute clonidine toxicity is necessary. Seizures can be managed with IV administration of a benzodiazepine (c.g., diazepam). Although forced diuresis has been suggested to enhance the elimination of clonidine, there is no current evidence to support this procedure for clonidine overdosage; in addition, forced diuresis may potentiate clonidine-induced hypotension. Hemodialysis is of limited value in the treatment of clonidine overdosage, since a maximum of 5% of circulating drug is removed.

Pharmacology

■ Cardiovascular Effects Clonidine appears to stimulate α_2 -adrenergic receptors in the CNS (mainly in the medulla oblongata), causing inhibition, but not blockade, of sympathetic vasomotor centers. Cardiovascular reflexes remain intact, and normal homeostatic mechanisms and hemodynamic responses to exercise are maintained. The central effects of the drug result in reduced peripheral sympathetic nervous system activity, reduced peripheral and renovascular resistance, reduction of systolic and diastolic blood pressure, and bradycardia. Peripheral venous pressure remains unchanged. It has been postulated that the hypotensive response to clonidine may result from reduced angiotensin II generation because of inhibition of renin release or from reduced stimulation of medullary vasomotor centers responsive to circulating angiotensin II; however, the exact relationship between the action of the drug in reducing renin activity and excretion of aldosterone and catecholamines and the hypotensive effect of the drug has not been fully elucidated.

Clonidine reduces blood pressure to essentially the same extent in both supine and standing patients; therefore, orthostatic effects are mild and infrequently encountered. However, the underlying hemodynamic effects differ with position of the patient. Administration of a single dose of clonidine hydrochloride to supine patients results in a reduction in cardiac output and decreased stroke volume. Total peripheral resistance remains unchanged. In patients in the standing position or at a 45° tilt, a smaller decrease in cardiac output occurs and total peripheral resistance is decreased, but stroke volume is maintained. Prolonged therapy results in circulatory adjustments, so that the hypotensive effect of the drug largely results from reduced peripheral resistance. Rapid IV, but not oral or IM, administration of clonidine produces direct stimulation of peripheral α_2 -adrenergic receptors, resulting in transient vasoconstriction and a rise in systolic and diastolic blood pressure.

Urinary excretion of catecholamines is decreased during clonidine hydrochloride therapy; however, unlike reserpine, clonidine does not deplete catecholamines from the heart or other tissues. Abrupt withdrawal of clonidine following prolonged oral administration may cause increased urinary excretion of catecholamines and rebound of systolic and diastolic blood pressure.

Blood volume, as determined using iodinated I 131 serum albumin, is not substantially affected by clonidine. Circulation time is prolonged during use of the drug.

- Analgesic Effect Epidurally administered α_2 -agonists, including clonidine, produce anagesia by mimicking the activation of descending pain-suppressing pathways arising from supraspinal control centers (i.e., cortex, thalamus, and brainstem) and terminating in the dorsal horn of the spinal cord. Stimulation of spinal α_2 -adrenergic receptors by clonidine inhibits sympathetically mediated ascending pain pathways that are activated by nociceptive stimuli and prevents transmission of pain signals to the brain. Activation of α_2 -adrenergic receptors by α_2 -adrenergic agonists also stimulates acetylcholine release and inhibits the release of substance P, an inflammatory neuropeptide. Clonidine-mediated analgesia is dose-dependent and is limited to regions of the body that are innervated by spinal segments containing analgesic concentrations of the drug. Analgesia resulting from clonidine therapy is not antagonized by opiate antagonists.
- Renal and Metabolic Effects Acute or chronic administration of clonidine hydrochloride produces no substantial change in renal blood flow, renal plasma flow, or glomerular filtration rate. In standing patients, renal vascular resistance is substantially reduced. The moderate reduction in renal blood flow and glomerular filtration rate produced by head-up tilting are unchanged by administration of the drug. The increased renal vascular resistance which normally occurs after tilting does not occur in patients receiving clonidine.

Sodium and chloride excretion are markedly reduced after initial adminstration of clonidine hydrochloride; however, potassium excretion is not substantially changed. Sodium retention probably results from enhanced tubular reabsorption being stimulated by decreased renal perfusion pressure and generally persists for only 3-4 days after which natriuresis occurs. Renal vein plasma renin activity and aldosterone excretion rate are consistently reduced as a result of centrally mediated sympathetic inhibition.

Other Effects Acute administration of clonidine stimulates release of growth hormone in children and adults, but the drug does not produce sustained elevation of growth hormone during chronic administration.

The sedative effect of clonidine is thought to result from central α_2 -agonist activity. The decrease in salivation induced by clonidine appears to result from both central and peripheral mechanisms, probably involving the drug's α_2 -agonist activity. The peripheral mechanism of decreased salivation may involve inhibition of cholinergic transmission via stimulation of α_2 -adrenergic receptors.

Clonidine has been shown to decrease GI motility and control diarrhea in animals, probably secondary to the drug's α_2 -agonist activity. Clonidine has also been shown to increase intestinal absorption of sodium and chloride, with a secondary passive increase in water absorption.

IV or topical administration of clonidine hydrochloride in patients with glaucoma decreases intraocular pressure, reportedly by decreasing production of aqueous humor. It has been reported that when only one eye is treated topically with clonidine, ocular pressure in the untreated eye is also reduced.

Clonidine has been shown to reduce the signs and symptoms of opiate withdrawal in individuals physically dependent on opiates. Clonidine appears to reduce the severity of opiate withdrawal symptoms by stimulating central presynaptic α_2 -adrenergic receptors; the stimulation results in attenuation in noradrenergic activity in the CNS, which may be responsible for the behavioral symptoms of opiate withdrawal.

Pharmacokinetics

■ Absorption Clonidine hydrochloride is well absorbed from the GI tract. The drug may also be absorbed when applied topically to the eye. Clonidine is well absorbed percutaneously following topical application of a transdermal system to the arm or chest. Plasma clonidine concentrations of 2 ng/mL have been detected 1 hour after administration of a single 0.39-mg oral dose of radiolabeled drug. Peak plasma concentrations following oral administration occur in approximately 3–5 hours.

Following initial application of a transdermal system of clonidine, the initial release of the drug saturates skin sites beneath the system; therapeutic plasma concentrations are attained within 2-3 days. To provide the concentration gradient necessary for controlled release and percutaneous absorption of drug, clonidine transdermal systems contain an excess amount of drug. Following removal of the systems in one study in healthy adults, analysis of residual concentration of drug in transdermal systems that initially contained 2.5 mg of clonidine per 3.5 cm2 surface area indicated that release of clonidine averaged 48 and 65% after 7 and 11 days of wear, respectively, following topical application to the upper outer arm and averaged 70% after 11 days of wear following topical application to the chest. When given in dosages that produce comparable blood pressure reduction, steady-state plasma clonidine concentrations attained with the transdermal systems are generally similar to trough concentrations attained with twice-daily oral dosing regimens of the drug. Mean steady-state plasma clonidine concentrations of 0.39, 0.84, or 1.12 ng/mL have been reported following topical application of the 3.5-, 7-, or 10.5-cm² transdermal system (see Preparations), respectively, to the upper outer arm of healthy adults. Percutaneous absorption of the drug from the upper arm or chest is similar, but less drug is absorbed from the thigh. Replacement of the transdermal system at a different site at weekly intervals continuously maintains therapeutic plasma clonidine concentrations. Following discontinuance of transdermal therapy, therapeutic plasma drug concentrations persist for about 8 hours and then decline slowly over several days; over this time period, blood pressure returns gradually to pretreatment levels. If a transdermal system of clonidine is not removed after 7 days as recommended, absorption of the drug from the system may continue; if an additional system is then applied, higher plasma drug concentrations may result and, if an additional system is not applied, plasma drug concentrations may not decrease substantially for at least 2-4 more days while the system is still being worn.

Reduction in blood pressure is maximal at plasma clonidine concentrations less than 2 ng/mL. Blood pressure begins to decrease within 30–60 minutes after an oral dose of clonidine hydrochloride; the maximum decrease occurs in approximately 2–4 hours. The hypotensive effect lasts up to 8 hours. Following administration of clonidine by slow IV injection† in patients with acute hypertensive crisis, a hypotensive effect occurred within minutes, peaked in 30–60 minutes, and lasted more than 4 hours.

Following epidural administration of a single bolus dose of clonidine in healthy individuals and patients with cancer, clonidine is rapidly absorbed into the systemic circulation. A mean peak plasma clonidine concentration of 4.4 ng/mL (range: 3–5.8 ng/mL) was reported on average 19 minutes following epidural administration of 700 mcg of clonidine hydrochloride given over 5 minutes in healthy individuals. Mean peak plasma concentrations of clonidine

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were reported to be higher in women than in men. Following continuous epidural infusion of clonidine hydrochloride (30 mcg/hour for 14 days in addition to administration of morphine sulfate for patient-controlled analgesia [PCA]) in cancer patients, mean steady-state plasma concentrations were approximately 2.2 and 2.4-2.5 ng/mL on days 7 and 14 of dosing, respectively. Accumulation of clonidine does not appear to occur following continuous epidural infusion of the drug in adult cancer patients.

Following epidural administration of a single dose of clonidine hydrochloride, near maximal analgesia occurs within 30-60 minutes. Onset and duration of the analgesic effect of a single epidural dose of clonidine do not correlate with plasma drug concentrations; rather, analgesic effects appear to correlate with drug concentration in the CSF. Although the CSF is not the presumed site of action of clonidine-mediated analgesia, the drug appears to diffuse rapidly from the CSF to the dorsal horn. A lumbar CSF concentration of 130 ng/mL reportedly was associated with a 95% maximal analgesic effect in healthy individuals.

Animal studies indicate that clonidine is widely distrib- Distribution uted into body tissues; tissue concentrations of the drug are higher than plasma concentrations. The mean volume of distribution of clonidine is reported to be 2.1 L/kg. After oral administration, highest concentrations of the drug are found in the kidneys, liver, spleen, and GI tract. High concentrations of the drug also appear in the lacrimal and parotid glands. Clonidine is concentrated in the choroid of the eye and is also distributed into the heart, lungs, testes, adrenal glands, fat, and muscle. The lowest concentration occurs in the brain. Clonidine is distributed into CSF. Following epidural infusion, clonidine is rapidly and extensively distributed into CSF and readily partitions into the plasma via epidural veins. In vitro, clonidine is approximately 20-40% bound to plasma proteins, mainly albumin. Clonidine crosses the placenta and is distributed into milk. In one lactating woman who received approximately 0.04 mg of oral clonidine hydrochloride twice daily and 25 mg of oral dihydralazine 3 times daily, clonidine concentrations were 0.33 ng/mL in a plasma sample obtained 1 hour after a dose and 0.6 ng/mL in a milk sample obtained 2.5 hours after a dose; the drug was not detected in the plasma of the infant 1 hour after nursing.

The plasma half-life of clonidine is 6-20 hours in patients Elimination with normal renal function. The half-life in patients with impaired renal function has been reported to range from 18-41 hours. The elimination half-life of the drug may be dose dependent, increasing with increasing dose.

Clonidine hydrochloride is metabolized in the liver. In humans, 4 metabolites have been detected but only one, the inactive p-hydroxyclonidine, has

been identified. In humans, 40-60% of an orally administered dose of clonidine hydrochloride is excreted in urine as unchanged drug within 24 hours. Following IV administration of radiolabeled clonidine, 72% of the administered dose is excreted in urine within 96 hours; about 40-50% is excreted as unchanged drug. In humans, less than 10% of a dose usually is excreted as p-hydroxyclonidine. Approximately 20% of the dose is excreted in feces, probably via enterohepatic circulation. Approximately 85% of a single dose is excreted within 72 hours, and excretion is complete after 5 days. Following IV administration of clonidine, renal clearance of the drug averages 133 mL/minute. In patients undergoing hemodialysis, only 5% of a dose was removed into the dialysate. Following continuous epidural infusion of clonidine hydrochloride (30 mcg/hour for 14 days in addition to morphine sulfate administered for patient-controlled analgesia [PCA]) in cancer patients, mean total body clearance of the drug was approximately 279 and 272 mL/minute on days 7 and 14 of dosing, respectively.

Chemistry and Stability

Chemistry Clonidine hydrochloride, an imidazoline-derivative hypotensive agent, is a selective α_2 -adrenergic agonist. Clonidine is commercially available as the base and as the hydrochloride salt. Clonidine hydrochloride occurs as a white, crystalline powder that has a bitter taste and is freely soluble in water and soluble in alcohol. Clonidine hydrochloride also is commercially available as a clear, colorless, preservative-free aqueous sterile solution. Sodium hydroxide and/or hydrochloric acid may be added during manufacture of the injection to adjust the pH to 5-7.

The commercially available transdermal system of clonidine consists of an outer layer of pigmented polyester film; a drug reservoir of clonidine, mineral oil, polyisobutylene, and colloidal silicon dioxide; a microporous polypropylene membrane that controls the rate of diffusion of the drug; and a final adhesive layer that provides an initial release of drug and contains those ingredients found in the reservoir. The adhesive layer is covered by a protective

strip which is removed prior to application.

The commercially available transdermal system of clonidine Stability should be stored at a temperature less than 30°C. Clonidine hydrochloride tablets should be stored in tight, light-resistant containers at a temperature less than 30°C. Commercially available clonidine hydrochloride tablets have an expiration date of 42 months following the date of manufacture. Commercially available clonidine hydrochloride injection should be stored at controlled room temperature (15-30°C). The injection contains no preservatives; any unused portion should be discarded.

Preparations

Clonidine

Topical

Transdermal System

0.1 mg/24 hours (2.5 mg/3.5

cm2)

Catapres-TTS®, Boehringer Ingelheim Catapres-TTS*, Boehringer

0.2 mg/24 hours (5 mg/7

Ingelheim

0.3 mg/24 hours (7.5 mg/10.5 Catapres-TTS*, Boehringer

Ingelheim

Clonidine Hydrochloride

Oral

Tablets

0.1 ma⁴

Cataprese (with parabens; scored), Boehringer Ingelheim

Clonidine Hydrochloride Tablets, Mylan, Purepac, UDL

0.2 ma

Catapres® (with parabensscored), Boehringer

İngelheim

Clonidine Hydrochloride Tablets, Mylan, Purepac, UDL

0.3 ma

Catapres® (with parabensscored), Boehringer

Ingelheim

Clonidine Hydrochloride Tablets, Mylan, Purepac, UDL

Parenteral

For Injection, 500 mcg/mL for epidural

Duracion* (preservative-free),

Roxane

concentrate

Injection, for epidural use

100 mcg/ml_

Duracion® (preservative-free), Roxane

Clonidine Hydrochloride and Chlorthalidone

Oral

Tablets

0.1 mg Clonidine Hydrochloride and

Chlorthalidone 15 mg

0.2 mg Clonidine Hydrochloride and Chlorthalidone 15 mg

0.3 mg Clonidine Hydrochloride and Chlorthalidone 15 mg Clorpres® (scored), Bertek

Clorpres® (scored), Bertek

Clorpres* (scored), Bertek

†Use is not currently included in the labeling approved by the US Food and Drug Administration Selected Revisions January 2004, © Copyright, October 1975, American Society of Health-System Pharmacists, Inc.

Guanabenz Acetate

 Guanabenz acetate is a centrally active hypotensive agent that is structurally and pharmacologically related to clonidine.

Uses

■ Hypertension Guanabenz is used alone or in combination with other classes of antihypertensive agents in the management of hypertension. Thiazide diuretics, however, are considered the preferred initial monotherapy for uncomplicated hypertension by the Joint National Committee (JNC 7) on the Prevention, Detection, Evaluation, and Treatment of Hypertension in the US. (See Uses: Hypertension, in the Thiazides General Statement 40:28.)

The efficacy of guanabenz in hypertensive patients is similar to that of other adrenergic agonists such as clonidine, methyldopa, or β -adrenergic blocking agents (e.g., pindolol, propranolol). As with other hypotensive agents, treatment with guanabenz is not curative; after withdrawal of the drug, blood pressure returns to pretreatment levels or greater.

Although many hypertensive patients may be controlled by guanabenz alone, the drug may be more effective when used with a diuretic. Guanabenz has been used in conjunction with thiazide diuretics, producing a greater re-

^{*}available by nonproprietary name

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UNITED STATES DISTRICT COURT EASTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA, and THE STATE OF WISCONSIN, ex rel. DR. TOBY TYLER WATSON,
Plaintiffs, v. Case No. 11-CV-236
JENNIFER KING VASSEL,
Defendant.
AFFIDAVIT OF JENNIFER KING, M.D. IN SUPPORT OF HER OPPOSITION TO THE PLAINTIFF'S MOTION FOR ENTRY OF AN HIPAA QUALIFIED PROTECTIVE ORDER FOR CUSTODIANS OF HER PATIENT RECORDS
STATE OF WISCONSIN)) ss. COUNTY OF MILWAUKEE)
JENNIFER KING, M.D., being duly sworn under oath, deposes and states as follows:
1. This affidavit is submitted in support of affiant's opposition to the plaintiff's motion.
2. A prescription is approved for reimbursement pursuant to a formulary or prior
authorization.
s/Jennifer King, M.D. Jennifer King, M.D.
Subscribed and sworn to before me this 29th day of October, 2013.
s/Bradley S. Foley Notary Public, State of Wisconsin

My Commission is permanent.