



IMPORTANT DRUG INFORMATION

April 22, 2004

Dear Health Care Provider,

In 2003, the Food and Drug Administration (FDA) asked all manufacturers of atypical antipsychotic medications, including AstraZeneca Pharmaceuticals LP (AstraZeneca), to add a Warnings statement describing the increased risk of hyperglycemia and diabetes in patients taking these medications, including SEROQUEL® (quetiapine fumarate) Tablets. AstraZeneca added the FDA Warnings statement to its SEROQUEL Prescribing Information and communicated that change to you in a letter dated January 30, 2004.

It has come to the attention of AstraZeneca that the Warnings statement set forth in its January 30, 2004 letter did not quote in its entirety the new Warnings statement included in the Prescribing Information; the words “and periodically during treatment” were omitted from the end of the second sentence of the second paragraph of the warning. Accordingly, enclosed is a new letter dated April 22, 2004, which quotes the Warnings statement from the Prescribing Information in its entirety.

Please discard the January 30, 2004 letter and replace it with the enclosed letter.

Sincerely,

A handwritten signature in black ink that reads "Wayne Macfadden MD".

Wayne Macfadden, MD
US Medical Director, SEROQUEL

219669



IMPORTANT DRUG INFORMATION

April 22, 2004

Dear Health Care Provider,

AstraZeneca Pharmaceuticals LP would like to inform you of important labeling changes regarding SEROQUEL® (quetiapine fumarate). The FDA has asked all manufacturers of atypical antipsychotic medications, including AstraZeneca, to add a Warnings statement describing the increased risk of hyperglycemia and diabetes in patients taking these medications, including SEROQUEL. Accordingly, the SEROQUEL Prescribing Information has been updated with the addition of the following information:

WARNINGS

Hyperglycemia and Diabetes Mellitus

Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics, including Seroquel. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics. Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available.

Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (eg, obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug.

AstraZeneca remains committed to providing you with the most current product information available for the management of your patients. You may immediately review the Warnings statement about hyperglycemia and diabetes mellitus in the SEROQUEL Prescribing Information by visiting the web site at www.Seroquel.com. Updated package inserts containing the additional hyperglycemia and diabetes mellitus information will accompany the medication in the near future and you should, of course, refer to the insert for full Prescribing Information.

As always, we request that serious adverse events be reported to AstraZeneca at 1-800-236-9933 or to the FDA MedWatch program at 1-800-FDA-1088, by fax at 1-800-FDA-0178, or by e-mail at www.fda.gov/medwatch. For additional medical information about SEROQUEL, please call 1-800-236-9933 from 9:00 am to 5:00 pm EST, Monday through Friday.

Sincerely,

A handwritten signature in cursive script, appearing to read "W Macfadden MD".

Wayne Macfadden, MD

US Medical Director, SEROQUEL