JANSSEN PHARMACEUTICA INC.

IMPORTANT CORRECTION OF DRUG INFORMATION

July 21, 2004

Dear Health Care Provider:

The Food and Drug Administration's (FDA) Division of Drug, Marketing, Advertising, and Communications (DDMAC) has asked us to contact you because Janssen Pharmaceutica Products, L.P. recently received a Warning Letter concerning the promotion of Risperdal® (risperidone). This letter provides important corrective information about Risperdal relating to hyperglycemia and Diabetes Mellitus.

The Warning Letter concludes that Janssen disseminated a Risperdal Dear Health Care Provider (DHCP) dated November 10, 2003 that omitted material information about Risperdal, minimized potentially fatal risks, and made misleading claims suggesting superior safety to other atypical antipsychotics without adequate substantiation, in violation of the Federal Food, Drug and Cosmetic Act.

Specifically, the Warning Letter stated that the DHCP letter omitted important information regarding hyperglycemia and diabetes, including the potential consequences and the recommendation of regular glucose control monitoring that was added to the approved product labeling for Risperdal; minimized the potentially fatal risks of hyperglycemia-related adverse events such as ketoacidosis, hyperosmolar coma and death; minimized the importance of blood glucose monitoring; suggested that Risperdal did not increase the risk of diabetes, contradicting the Warning in the revised product labeling; and made misleading claims suggesting that Risperdal has a lower risk of hyperglycemia and diabetes than other atypical antipsychotics without adequate substantiation which is inconsistent with the Prescribing Information for Risperdal.

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In order to provide you with complete and accurate information regarding hyperglycemia and Diabetes Mellitus relative to Risperdal, please be advised that the Risperdal Prescribing Information was updated with the addition of the Warning in November 2003.

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 RISPERDAL®. 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 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 (e.g., 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.

If you have any questions regarding this important safety information, please contact Janssen Medical Affairs at 1-800-JANSSEN. Please refer to the full prescribing information for Risperdal included with this letter. As always, we request that serious adverse events be reported to Janssen at 1-800-JANSSEN or the FDA MedWatch program by phone (1-800-FDA-0178), or by e-mail (www.fda.gov).

Sincerely,

Ramy Mahmoud, MD, MPH
Vice President, CNS
Janssen Medical Affairs, LLC
Enclosure: Risperdal Package Insert