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Pfizer Global Pharmaceuticals

IMPORTANT PRESCRIBING INFORMATION

Dear Healthcare Practitioner:

The Food and Drug Administration requested that a warning be added to the prescribing information for all atypical antipsychotics regarding the risk of hyperglycemia and diabetes. This warning advises in part that hyperglycemia, in some cases extreme, has been reported in patients treated with atypical antipsychotics. Attached for your review is the updated full GEODON (ziprasidone) prescribing information.

The new warning provides information that is specific to GEODON, hyperglycemia, and related adverse events:

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. There have been few reports of hyperglycemia or diabetes in patients treated with GEODON. Although fewer patients have been treated with GEODON, it is not known if this more limited experience is the sole reason for the paucity of such reports. 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, which did not include GEODON, suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics included in these studies. Because GEODON was not marketed at the time these studies were performed, it is not known if GEODON is associated with this increased risk. 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 antidiabetic treatment despite discontinuation of the suspect drug.

While, as noted above, there have been few reports of hyperglycemia or diabetes in patients treated with GEODON, an exhaustive review of the GEODON database revealed no increased signal for diabetes. Additional information is needed to confirm this. However, as noted in the new warning, it is prudent to monitor patients treated with atypical antipsychotics for signs and symptoms of diabetes. Patients with risk factors for diabetes mellitus (eg, obesity, family history) who are starting treatment with atypical antipsychotics should undergo baseline screening and routine monitoring throughout therapy to mitigate the risk of developing serious metabolic complications. GEODON is indicated for the treatment of schizophrenia.

Pfizer continues to be committed to working with health authorities including FDA to assure that appropriate evidence-based information is included in prescribing information for GEODON (ziprasidone).

Please see accompanying full Prescribing Information included with this letter.

For additional information about GEODON, call 1-800-438-1985.

Sincerely,

A handwritten signature in black ink that reads "Cathryn M. Clary" followed by a stylized initial "D".

Cathryn M. Clary, MD, MBA
Vice President
Psychiatry, Neurology
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