



FDA News

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FDA Requires Boxed Warning and Risk Mitigation Strategy for Metoclopramide-Containing Drugs

Agency warns against chronic use of these products to treat gastrointestinal disorders

The U.S. Food and Drug Administration announced today that manufacturers of metoclopramide, a drug used to treat gastrointestinal disorders, must add a boxed warning to their drug labels about the risk of its long-term or high-dose use. Chronic use of metoclopramide has been linked to tardive dyskinesia, which may include involuntary and repetitive movements of the body, even after the drugs are no longer taken.

Manufacturers will be required to implement a risk evaluation and mitigation strategy, or REMS, to ensure patients are provided with a medication guide that discusses this risk.

"The FDA wants patients and health care professionals to know about this risk so they can make informed decisions about treatment," said Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research. "The chronic use of metoclopramide therapy should be avoided in all but rare cases where the benefit is believed to outweigh the risk."

Current product labeling warns of the risk of tardive dyskinesia with chronic metoclopramide treatment. The development of this condition is directly related to the length of time a patient is taking metoclopramide and the number of doses taken. Those at greatest risk include the elderly, especially older women, and people who have been on the drug for a long time.

Tardive dyskinesia is characterized by involuntary, repetitive movements of the extremities, or lip smacking, grimacing, tongue protrusion, rapid eye movements or blinking, puckering and pursing of the lips, or impaired movement of the fingers. These symptoms are rarely reversible and there is no known treatment. However, in some patients, symptoms may lessen or resolve after metoclopramide treatment is stopped.

Metoclopramide works by speeding up the movement of the stomach muscles, thus increasing the rate at which the stomach empties into the intestines. It is used as a short-term treatment of gastroesophageal reflux disease in patients who have not responded to other therapies, and to treat diabetic gastroparesis (slowed emptying of the stomach's contents into the intestines). It is recommended that treatment not exceed three months.

Metoclopramide is available in a variety of formulations including tablets, syrups and injections. Names of metoclopramide-containing products include Reglan Tablets, Reglan Oral Disintegrating Tablets, Metoclopramide Oral Solution, and Reglan Injection. More than two million Americans use these products.

Recently published analyses suggest that metoclopramide is the most common cause of drug-induced movement disorders. Another analysis of study data by the FDA showed that about 20 percent of patients in that study who used metoclopramide took it for longer than three months. The FDA has also become aware of continued spontaneous reports of tardive dyskinesia in patients who used metoclopramide, the majority of whom had taken the drug for more than three months.

Consumers and health care professionals are encouraged to report adverse events to the FDA's MedWatch program at 800-FDA-1088, by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, Md. 20852-9787, or online at: www.fda.gov/medwatch/report.htm

For information about REMS see: [Public Law 110-85](#)

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