

FDA notified healthcare professionals 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. These symptoms are rarely reversible and there is no known treatment. 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. Manufacturers will be required to implement a risk evaluation and mitigation strategy [REMS] to ensure patients are provided with a medication guide that discusses this risk. Current product labeling warns of the risk of tardive dyskinesia with chronic metoclopramide treatment.

Read the MedWatch 2009 safety summary, including a link to the FDA News Release, at:

<http://www.fda.gov/medwatch/safety/2009/safety09.htm#Metoclopramide>

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