

UPDATE 1-US FDA: Stomach drugs need movement disorder warning

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WASHINGTON, Feb 26 (Reuters) - A class of drugs to treat stomach disorders needs a strong warning about the risk of involuntary, repetitive movement on several parts of the body seen with long-term use or high doses, U.S. regulators said on Thursday.

The drugs contain the ingredient metoclopramide and are available in various forms including tablets, syrups and injections, the Food and Drug Administration said. Makers include Baxter International Inc ([BAX.N](#)) and several generic drug companies.

More than 2 million Americans use the medicines to treat gastroesophageal reflux disease and other stomach ailments, the FDA said.

Chronic use has been linked to tardive dyskinesia, which causes repetitive movements of the limbs, lip smacking, grimacing, tongue protrusion and rapid eye movements and blinking. The symptoms are rarely reversible but may lessen or resolve after metoclopramide treatment ends, the FDA said.

The agency ordered manufacturers to add a "black box" warning, the strongest available, and develop a patient-friendly guide explaining the risk.

The FDA recommended that treatment not exceed three months because the risk of the movement disorder was "directly related to the length of time a patient is taking metoclopramide and the number of doses taken." The elderly, especially older women, face greater risks, the agency said.

"The chronic use of metoclopramide therapy should be avoided in all but rare cases where the benefit is believed to outweigh the risk," Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research, said in a statement.

Baxter spokeswoman Erin Gardiner said the company would add the warning to its product, an injectable version sold under the brand name Reglan.

She said the company had not seen an increase in reports of tardive dyskinesia, which is a known but rare side effect already mentioned in the drug's prescribing instructions. Annual U.S. sales are about \$2 million, she said. (Reporting by Lisa Richwine, editing by Tim Dobbyn, Bernard Orr)