

**CLIP&COPY**<sup>®</sup>  
NEWS THAT WORKS FOR YOU.  
[www.ClipandCopy.com](http://www.ClipandCopy.com)



The online clipping service  
that lets **you**  
use the news.

**AP** Associated Press

February 26, 2009

## FDA slaps warning on heartburn drug tied to spasms

Federal health officials are adding their sternest warning to a heartburn drug that has been linked to muscle spasms.

The Food and Drug Administration said the drug, widely known as Reglan, has been shown to cause spasms and tics when used for long periods of time or at high doses. The problems include uncontrollable movement of the limbs, face and tongue, and are usually irreversible, even after patients stop taking the drug, according to the FDA's warning.

The agency is requiring drugmakers to add a black box warning, the most serious type available, to their products.

Manufacturers also will be required to distribute medication safety guides to patients.

The drug was marketed by Wyeth for a number of years. However, the Madison, N.J.-based company sold the tablet form to Schwarz Pharma in 2001 and the injectable form to Baxter International in 2002. The drug also is marketed by a number of generic companies.

The drug's current labeling already mentions risks of developing the spasms, called dyskinesia, but the agency's action Thursday elevates the warning to the top of the label. Reglan, known generically as metoclopramide, comes in a variety of forms, including injections and edible syrups. The drug works by speeding up the muscles used in digestion and relieving painful stomach acid reflux.

More than 2 million U.S. patients use the drugs, according to the FDA.

"The chronic use of metoclopramide therapy should be avoided in all but rare cases where the benefit is believed to outweigh the risk," said Dr. Janet Woodcock, director of FDA's drug center.

Regulators said patients who face the greatest risks include the elderly, especially women, and those who have been taking the drug for more than three months.

The agency based its decision on recently published studies suggesting metoclopramide is the leading cause of pharmaceutical-related movement disorders. One study showed that roughly 20 percent of patients who take the drug longer than three months develop dyskinesia.

(This version CORRECTS that drug is no longer marketed by Wyeth.)

 © 2009 Associated Press. Permission granted for up to 5 e-mails. All rights reserved.

You may forward this article or get additional permissions by typing [http://license.icopyright.net/3.5721?icx\\_id=D96JHC600](http://license.icopyright.net/3.5721?icx_id=D96JHC600) into any web browser. Press Association and Associated Press logos are registered trademarks of Press Association . The iCopyright logo is a registered trademark of iCopyright, Inc.