FDA OKs first generic version of heartburn drug nexium

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The proton pump inhibitor reduces amount of acid in the stomach.

(HealthDay)—The first generic version of the heartburn drug Nexium (esomeprazole) has been approved by the U.S. Food and Drug Administration.

Ivax Pharmaceuticals Inc., a subsidiary of Teva Pharmaceuticals U.S.A., received approval to market esomeprazole in 20- and 40-milligram capsules to treat gastroesophogeal reflux disease (GERD) in adults and children ages 1 and older, the FDA said Monday.

GERD stands for gastroesophageal reflux disease. GERD occurs when stomach acid backs into the esophagus, and is commonly known as chronic heartburn or acid reflux.

The capsules are also approved to reduce the risk of stomach ulcers associated with use of nonsteroidal anti-inflammatory drugs (NSAIDs, such as aspirin, naproxen and ibuprofen). The capsules are also approved to treat the stomach infection *Helicobacter pylori*, along with certain antibiotics, and to treat conditions where the stomach makes too much acid, according to the FDA.

Esomeprazole is a proton pump inhibitor that reduces the amount of acid in the stomach.

"Health care professionals and consumers can be assured that these FDA-approved generic drugs have met our rigorous standards," Dr. Kathleen Uhl, director of the Office of Generic Drugs in the FDA's Center for Drug Evaluation and Research, said in an agency news release.

"It is important for patients to have access to treatment options for chronic conditions," she added.

The most serious risks when taking esomeprazole are stomach problems, including severe diarrhea. Also, people who take proton pump inhibitors for long periods of time are at increased risk for bone fractures, the FDA said.

More information: The U.S. National Library of Medicine has more about GERD.