Lansoprazole Delayed-Release Orally Disintegrating Tablets by Teva Pharmaceuticals: Letter to Healthcare Professionals - Clogged, Blocked Oral Syringes and Feeding Tubes

U.S. Food & Drug Administration

AUDIENCE: Risk Manager, Pharmacy, Home Care

ISSUE: The FDA has received reports that Teva's lansoprazole delayed-release orally disintegrating tablet has clogged and blocked oral syringes and feeding tubes, including both gastric and jejunostomy types, when the drug is administered as a suspension through these devices. The tablets may not fully disintegrate when water is added to them and/or they may disintegrate but later form clumps. These clumps can adhere to the inside walls of oral syringes and feeding tubes. In some cases, patients have had to seek emergency medical assistance and their feeding tubes have had to be unclogged or removed and replaced.

BACKGROUND: Lansoprazole is a proton pump inhibitor (PPI) medication. It is approved for the treatment of gastric and duodenal ulcers, gastroesophageal reflux disease (GERD), erosive esophagitis (EE), and Zollinger-Ellison Syndrome (a condition involving overproduction of stomach acid).

Teva Pharmaceuticals has voluntarily withdrawn its lansoprazole delayed-release ODT product from distribution at this time. However, some product may remain in stock in pharmacies and other facilities, and some patients may still have the product in their possession. The product may also be sold under the following labels: Sharp Corporation, Cardinal Health, and Quality Packaging Specialist, Inc.

RECOMMENDATIONS:

- FDA recommends that healthcare professionals evaluate their medication stock and not dispense the Teva lansoprazole delayed-release ODT product to patients for whom the product will be administered through an oral syringe or feeding tube.
- Patients and caregivers should be instructed not to administer the Teva lansoprazole delayed-release ODT product through oral syringes and/or feeding tubes due to the potential for clogging and blockage of the oral syringe or tube.
- Read the Healthcare Professional Letter for other specific recommendations and for National Drug Code (NDC) numbers for the affected Teva products.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm [1]
- Download form [2] or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[04/15/2011 - Letter to Healthcare Professionals [3] - FDA]

SOURCE [4]

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http://www.mdtmag.com/news/2011/04/lansoprazole-delayed-release-orally-disintegrating-tablets-teva-pharmaceuticals-letter-healthcare-professionals-clogged-blocked-oral-syringes-and-feeding-tubes

Links:
[1] http://www.fda.gov/MedWatch/report.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
[3] http://www.fda.gov/Drugs/DrugSafety/ucm251485.htm
[4] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm251575.htm