AMERICAN HEALTH CARE

DRUG PRODUCTS & SAFETY NEWS

Zecuity Safety Communication Update

June 13, 2016

Zecuity manufacturer Teva Pharmaceuticals has decided to temporarily suspend sales, marketing, and distribution to investigate the cause of burns and scars associated with the Zecuity patch. Health care professionals should discontinue prescribing Zecuity, and patients should stop using any remaining patches and contact their prescribers for an alternative migraine medicine.

The U.S. Food and Drug Administration (FDA) is investigating the risk of serious burns and potential permanent scarring with the use of Zecuity (sumatriptan iontophoretic transdermal system) patch for migraine headaches. Since marketing of the Zecuity patch began in September 2015, a large number of patients have reported they experienced burns or scars on the skin where the patch was worn. The reports included descriptions of severe redness, pain, skin discoloration, blistering, and cracked skin. As a result, FDA is investigating these serious adverse events to determine whether future regulatory action is needed, and will update the public with new information when the FDA review is complete.

The Zecuity patch contains the active ingredient sumatriptan, a prescription medicine used to treat acute migraine headaches in adults. The patch delivery system is designed to deliver a dose of medicine by way of a single-use, battery-powered patch that is wrapped around the upper arm or thigh. It should remain in place for no longer than four hours.

Patients who experience moderate to severe pain at the Zecuity patch site should immediately remove it to avoid possible burns or scarring, regardless of how long the patch has been worn, and contact your health care professional. Do not bathe, shower, or swim while wearing the patch. Read the Patient Information leaflet and the Instructions for Use section in the drug label, and talk with your health care professional if you have any questions or concerns.

Healthcare professionals and patients are encouraged to report any adverse events or side effects related to the use of this product and/or quality problems to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- ✓Complete and submit the report online: www.fda.gov/MedWatch/report.htm
- ✓Complete and return a form by mail (address on the pre-addressed form) or fax (1-800-FDA-0178).

[Call 1-800-332-1088 to request a reporting form or download a form at http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm.]

Source:
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm504736.htm

3850 Atherton Road, Rocklin CA 95765 ■ Member Services (800) 872-8276 ▪ Office (916) 773-7227 ▪ Fax (916) 773-7210
TDD/TTY (866) 571-6106 or (916) 960-0161 ■ Compliance Hotline (866) 532-0657
www.AmericanHealthCare.com