



Pharmaceuticals

IMPORTANT PRESCRIBING INFORMATION

URGENT – ZECUITY® (SUMATRIPTAN IONTOPHORETIC TRANSDERMAL SYSTEM) SUSPENSION OF MARKETING

June 10, 2016

Subject: Voluntary suspension of the sale, marketing, and distribution of ZECUITY® (sumatriptan iontophoretic transdermal system) due to reported cases of serious application site reactions

Dear Health Care Provider:

The purpose of this letter is to inform you that we are suspending the sale, marketing and distribution of ZECUITY® (sumatriptan iontophoretic transdermal system), indicated for the acute treatment of migraine with or without aura in adults. Teva has received postmarketing reports of application site reactions described as “burn” and/or “scar” in patients treated with ZECUITY. Descriptions of these reactions have included severe redness, cracked skin, blistering or welts, and burns or scars where the patch was worn. Patients described severe pain, itching, or burning. Although many cases resolved within hours to weeks, there are reports of cases with unresolved skin reactions, typically skin discoloration, after several months.

Teva has been working closely with the FDA to examine reported adverse skin reactions associated with ZECUITY usage. At Teva, we are deeply committed to the safety and well-being of people who use our products. As such, we have decided to engage in a voluntary suspension of the sale, marketing, and distribution of ZECUITY while we continue our investigations into the root cause of these adverse skin reactions. In keeping with this market suspension, we have initiated a pharmacy-level recall of the product.

Prescriber Action

- Discontinue prescribing of ZECUITY.
- Instruct patients to discontinue use of ZECUITY and evaluate patients and application site reactions as needed.

- Inform your patients of the availability of Migraine Support Solutions 1-855-ZECUITY (1-855-932-8489) for information and instructions regarding the disposition of unused ZECUITY patches.

Reporting Adverse Events

Health care providers and patients are encouraged to report adverse events in patients that have taken ZECUITY to Teva Pharmaceuticals at 1-800-896-5855. Adverse events or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting Program either online, or regular mail, or by fax:

- Complete and submit the report **Online:** www.fda.gov/medwatch/report.htm
- **Regular mail or Fax:** Download form www.fda.gov/MedWatch/getforms.htm 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.

This letter is not intended as a complete description of the benefits and risks related to the use of Zecuity. Please refer to the enclosed full prescribing information and patient information.

You also may contact our medical information department at 1-800-896-5855 if you have any questions about the information contained in this letter.

Thank you for taking the time to read about this important information on the market suspension of ZECUITY. Teva is committed to providing healthcare professionals with useful information to guide the safe and appropriate use of its products. If you have any questions, please contact Teva Medical Information at 1-800-896-5855, and we will be glad to assist you.

Sincerely,



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