



**[06-10-2016]** 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.

### FDA Drug Safety Communication

FDA evaluating the risk of burns and scars with Zecuity (sumatriptan) migraine patch

### Safety Announcement

**[06-02-2016]** 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. We are investigating the cause and extent of these serious side effects and will update the public with new information when our review is complete.

**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.

**Health care professionals** should advise patients who complain of moderate to severe pain at the application site to remove the Zecuity patch immediately. Consider a different formulation of sumatriptan or switch these patients to an alternative migraine medicine. Evaluate patients and the application site as needed.

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.

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, we are investigating these serious adverse events to determine whether future regulatory action is needed.

We urge patients and health care professionals to report possible side effects involving the Zecuity patch to the FDA MedWatch program, using the information in the “Contact FDA” box at the bottom of the page.

## **Related Information**

- [The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective](#)
- [Think It Through: Managing the Benefits and Risks of Medicines](#)