U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Drug Safety Communications

FDA Drug Safety Communication: FDA approves brand name change for antidepressant drug Brintellix (vortioxetine) to avoid confusion with antiplatelet drug Brilinta (ticagrelor)

This is an update to the FDA Drug Safety Communication: FDA warns about prescribing and dispensing errors resulting from brand name confusion with antidepressant Brintellix (vortioxetine) and antiplatelet Brilinta (ticagrelor) issued on July 30, 2015.

Safety Announcement

[05-02-2016] The U.S. Food and Administration (FDA) has approved a brand name change for the antidepressant Brintellix (vortioxetine) to decrease the risk of prescribing and dispensing errors resulting from name confusion with the blood-thinning medicine Brilinta (ticagrelor). The new brand name of the drug will be Trintellix, and it is expected to be available starting in June 2016. No other changes will be made to the label or packaging, and the medicine is exactly the same.

Because of the lag time associated with manufacturing bottles with the new brand name, health care professionals and patients may continue to see bottles labeled with the brand name Brintellix during the transition period.

Health care professionals should check carefully to make sure they have prescribed or dispensed the correct medicine. During the transition to the new name change from Brintellix to Trintellix, prescribers can reduce the risk of name confusion by including the generic name of the medication they are ordering, in addition to the brand name and indication for use. **Patients** should make sure they have received the correct medicine. Trintellix tablets will look the same as the Brintellix tablets. Those having any questions or concerns should talk to their prescriber or pharmacist.

Brintellix/Trintellix (vortioxetine) is used to treat a certain type of depression called major depressive disorder in adults. It is in a class of antidepressants called serotonin reuptake inhibitors (SSRIs) that work by affecting chemicals in the brain that may become unbalanced.

In a July 2015 Drug Safety Communication, we warned that name confusion between Brintellix and Brilinta had resulted in prescribing and dispensing errors since Brintellix was approved in September 2013. Due to continued reports of name confusion between the two medicines used for very different purposes, FDA worked with Brintellix manufacturer Takeda Pharmaceuticals to change the drug's brand name.

Individuals responsible for ordering and stocking the medicine should be aware that Trintellix will have a new National Drug Code (NDC) number. It is important for drug information content publishers and medication-related electronic system administrators to use the new brand

name Trintellix and NDC number once Takeda makes vortioxetine available under the new name Trintellix.

We urge health care professionals and patients to report name confusion, medication errors, and any side effects involving Brintellix/Trintellix or Brilinta to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of the page.

Data Summary

Since the July 2015 Drug Safety Communication, our review of the FDA Adverse Event Reporting System (FAERS) database has identified five additional cases describing brand name confusion involving Brintellix and Brilinta, bringing the total to 55 cases.

Two of these five new cases reported the following serious adverse drug events; the others were non-serious:

- In the most serious case, a patient had bleeding and partial collapse of a lung following a lung biopsy. The patient had been taking Brilinta (ticagrelor), but the medical staff confused it with Brintellix in the patient's medication record. As a result, the staff had not been aware the patient was on an antiplatelet agent at the time of the biopsy, and necessary precautions were not taken.
- In the other case, a geriatric patient was dispensed Brintellix in place of Brilinta. After ingesting Brintellix for nine days, the patient fell and was admitted to the hospital. The fall may have resulted from dizziness, a known adverse reaction with Brintellix.

Related Information

The FDA's Drug Review Process: Ensuring Drugs are Safe and Effective
http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143534.htm

Thinking it Through: Managing the Benefits and Risks of Medicines
http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143558.htm