

FDA Drug Safety Communication: FDA warns about prescribing and dispensing errors resulting from brand name confusion with antidepressant Brintellix (vortioxetine) and antiplatelet Brilinta (ticagrelor)

Safety Announcement

[07-30-2015] The U.S. Food and Drug Administration is warning health care professionals and patients that reports of confusion between the antidepressant Brintellix and anti-blood clotting medication Brilinta have resulted in the wrong medication being prescribed or dispensed. We have determined that the main reason for the confusion between these two medications is the similarity of their brand (proprietary) names. None of the reports indicates that a patient ingested the wrong medication; however, reports of prescribing and dispensing errors continue. As a result, we are alerting the public about this safety issue.

Health care professionals can reduce the risk of name confusion by including the generic (established) name of the medication, in addition to the brand name, and the indication for use when prescribing these medications. Patients should check their prescriptions to ensure that the correct medication was dispensed (See Additional Information for Patients and Caregivers for more detailed recommendations).

Brintellix (vortioxetine) is used to treat a certain type of depression called major depressive disorder (MDD) in adults. It is in a class of antidepressants called selective serotonin reuptake inhibitors (SSRIs) that work by affecting chemicals in the brain that may become unbalanced. Brintellix is a tear-shaped tablet stamped with “TL” on one side of the tablet and a number that indicates the tablet strength on the other side. It varies in color depending upon the strength prescribed.

Brilinta (ticagrelor) is an antiplatelet, anti-blood clotting medication used to lower the risk of having another heart attack, or dying from a heart problem after a heart attack or severe chest pain. It works by keeping the platelets in the blood from sticking together, thereby preventing blood clots that can occur with certain heart conditions. Brilinta is a round, yellow tablet with a “90” above a “T” stamped on one side.

As of June 2015, FDA has received 50 reports of medication error cases describing brand name confusion with Brintellix and Brilinta. Most of the cases reported concerns that similarities in the sound, look, or both sound and look of the two brand names could cause confusion for prescribers and pharmacists. Some cases resulted in the wrong medication being dispensed to a patient. In one case, a pharmacist misinterpreted Brintellix as Brilinta and did not dispense any medication because the patient had a contraindication to blood thinners.

We urge patients and health care professionals to report name confusion and medication errors involving Brintellix and Brilinta to the FDA MedWatch program, using the information in the “Contact FDA” box at the bottom of the page.

Facts about Brintellix (vortioxetine)

- Brintellix (vortioxetine) is used to treat a certain type of depression called major depressive disorder (MDD) in adults.
- Brintellix is in a class of antidepressants called selective serotonin reuptake inhibitors (SSRIs). It works by affecting chemicals in the brain that may become unbalanced.
- Brintellix is available in 5 mg, 10 mg, 15 mg, and 20 mg tablets.
- Brintellix is a tear-shaped tablet. The color and stamping depend upon the drug strength:
 - 5 mg tablet is pink and stamped with “5” and “TL”.
 - 10 mg tablet is yellow and stamped with “10” and “TL”.
 - 15 mg tablet is orange and stamped with “15” and “TL”.
 - 20 mg tablet is red and stamped with “20” and “TL”.
- The recommended starting dose of Brintellix is 10 mg once daily by mouth. The recommended target dose is 20 mg per day, as tolerated. A dose of 5 mg per day may be considered for patients who do not tolerate higher doses.
- Report any new or sudden changes in mood, behavior, thoughts, or feelings to your health care professional right away. This is very important when an antidepressant medication is started or when the dose is changed.
- Brintellix can increase the risk of abnormal bleeding or bruising. The risk of bleeding with Brintellix is further increased when it is used at the same time with other medications that can increase the risk of bleeding, which include:
 - Aspirin
 - Nonsteroidal anti-inflammatory drugs, or NSAIDs, such as ibuprofen
 - Blood-thinning anticoagulant and antiplatelet medications such as, but are not limited to, warfarin, clopidogrel, prasugrel, ticlopidine, and ticagrelor
- Common side effects can include nausea, dry mouth, constipation, and feeling bloated.
- Approximately 553,000 total prescriptions for Brintellix were dispensed from outpatient retail pharmacies in the United States from approval through April 2015.¹

Facts about Brilinta (ticagrelor)

- Brilinta (ticagrelor) is an antiplatelet medication used to lower the risk of having another heart attack, or dying from a heart problem after a heart attack or severe chest pain. Brilinta works by keeping the platelets in the blood from sticking together, thereby preventing blood clots that can occur with certain heart conditions.
- Brilinta is available in a 90 mg tablet.
- Brilinta is a round, yellow tablet with a “90” above a “T” stamped on it.
- The recommended Brilinta dose is 90 mg twice daily by mouth.
- Brilinta can increase the risk of bleeding:
 - Patients taking Brilinta may bleed and bruise more easily.
 - It will take longer than usual to stop bleeding.

- Patients taking Brilinta should tell their health care professionals about any bleeding that is unexpected, excessive or lasts longer than usual; or if they have blood in their stool or urine.
- Other common side effects can include shortness of breath.
- Approximately 976,000 total prescriptions for Brilinta were dispensed from outpatient retail pharmacies in the United States from approval through April 2015.¹

Additional Information for Patients and Caregivers

- Name confusion between Brintellix (vortioxetine) and Brilinta (ticagrelor) has resulted in some prescribing and dispensing errors. The brand names sound and appear similar, but the medications are used for very different purposes (See Facts About Brintellix and Brilinta sections).
- Check your prescription to ensure that the correct medication was dispensed:
 - Look at the name on the bottle.
 - Inspect the appearance of the tablet.
 - Know why you are taking it.
 - Ask questions to your health care professional if the name on the prescription, description of the medicine’s use, or appearance of the medication is different from what you expect.
- Brintellix is a tear-shaped tablet stamped with “TL” and a numeral that corresponds to the tablet strength (e.g. “5” for the 5 mg tablet). The color varies depending on the strength and may be pink, yellow, orange, or red.
- Brilinta is a round, yellow tablet with a “T” and a “90” stamped on it.
- Carefully read the patient Medication Guides that come with the [Brintellix](#) and [Brilinta](#) prescriptions. If the description of the medication’s use seems different from what you expected, ask your health care professional.
- Report any side effects from Brintellix or Brilinta to your health care professional and the FDA MedWatch program, using the information in the “Contact FDA” box at the bottom of the page.

Additional Information for Health Care Professionals

- Reports of brand name confusion and medication errors have been submitted for Brintellix (vortioxetine) and Brilinta (ticagrelor). Some of the contributing factors to the name confusion have included the following:
 - Both brand names begin with the same three letters.
 - Both brand names are presented as an option when selecting medications in a computerized physician order entry (CPOE) system.
 - The pharmacist was not familiar with the newer medication Brintellix and so dispensed Brilinta.
 - The brand names look and sound similar.
- To reduce the risk of name confusion when prescribing Brintellix or Brilinta, include:
 - Both the brand (proprietary) and generic (established) names
 - Indication
 - Correct medication dose

- Directions for use
- If prescribing Brintellix (vortioxetine):
 - Tell patients what the medication is used to treat.
 - Caution patients about clinical worsening and suicide risk, especially early during treatment and when adjusting the dose of the medication.
 - Caution patients about the increased risk of bleeding or bruising when Brintellix is co-administered with nonsteroidal anti-inflammatory drugs (NSAIDs), aspirin, or other medications that affect coagulation.
 - Caution patients about the risk of serotonin syndrome. Serotonin syndrome is more likely with the concomitant use of Brintellix and other serotonergic agents, including triptans, tricyclic antidepressants, fentanyl, Lithium, tramadol, tryptophan and St. John's Wort supplements.
- If prescribing Brilinta (ticagrelor):
 - Inform patients about the increased risk of bleeding and bruising.
 - Advise patients to report any unanticipated, prolonged or excessive bleeding, or blood in their stool or urine.
- Encourage patients and their caregivers to read the patient Medication Guides provided with their [Brintellix](#) and [Brilinta](#) prescriptions.
- Report adverse events involving Brintellix or Brilinta to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of the page.

Data Summary

As of June 2015, FDA has received 50 medication error reports describing brand name confusion with Brintellix (vortioxetine) and Brilinta (ticagrelor). In most cases, Brintellix was mistaken as Brilinta. Some of the contributing factors to the name confusion included the following:

- Both brand names begin with the same three letters.
- Both brand names are presented when selecting medications in a computerized physician order entry (CPOE) system.
- The pharmacist was not familiar with the new medication Brintellix and so dispensed Brilinta.
- The brand names look and sound similar.

Of these 50 reports of name confusion, the wrong medication was actually dispensed in 12 cases, and was possibly dispensed in three additional cases but could not be confirmed based on the case narrative information. None of the reports indicated a patient had ingested the wrong medication.

Although no ingestion of the wrong drug has been reported, in one case Brintellix was misinterpreted as Brilinta, resulting in a pharmacist not dispensing any medication due to the patient having a contraindication to antiplatelet therapy. As a result, the patient went untreated for the psychiatric indication for an unreported period.

In the 12 cases where a wrong medication was actually dispensed, the reports showed that:

- In six cases, the error occurred when prescribing the medication.

- Five of these prescribing errors occurred during computerized physician order entry. Some CPOE systems auto-populate or present a drop-down menu after the first three letters are typed, at which point a prescriber can select the wrong medication.
- In the other six cases, the error occurred during dispensing of the medication.

References

1. IMS Health, National Prescription Audit (NPA), SEPT2013-APR2015, Extracted JUN2015