

MEDICATION

A MONTHLY PUBLICATION FROM VA MEDSAFE:  
VA'S COMPREHENSIVE PHARMACOVIGILANCE CENTER

# SAFETY IN SECONDS

## Helping to achieve safe medication use

### LOOK-ALIKE NAME CONFUSION: BRILINTA (TICAGRELOR) AND BRINTELLIX (VORTIOXETINE)

ISMP received a report of a drug name look-alike error that occurred due to similar name confusion between Brilinta (ticagrelor) and Brintellix (vortioxetine). In this case, a provider attempted to electronically prescribe Brintellix (vortioxetine) for depression. When typing the first few letters of the brand name into the computer system, the provider incorrectly selected the antiplatelet agent Brilinta (ticagrelor) from the list of orderable items instead. The patient received the erroneous prescription for Brilinta (ticagrelor), but after reading the medication information, contacted the physician and exchanged her incorrect prescription for the intended Brintellix (vortioxetine). The patient did not take any doses of the wrong medication and did not report any adverse events.

Brilinta (ticagrelor) is a platelet inhibitor indicated for use in acute coronary syndrome (ACS) to reduce the risk of cardio-

vascular thromboembolic events while Brintellix (vortioxetine) is an antidepressant used to manage major depressive disorder. Brilinta (ticagrelor) has been associated with significant and sometimes fatal bleeding as stated in the boxed warning of the product's labeling. Inadvertent use of Brilinta (ticagrelor) instead of Brintellix (vortioxetine) may cause unintended bleeding in susceptible patients, such as those with older age, active pathological bleeding, history of intracranial hemorrhage, history of other bleeding disorders, planned invasive procedures (i.e., percutaneous invasive procedures), concomitant use of medications that increase the risk of bleeding (i.e., anticoagulant and/or fibrinolytic therapy, non-steroidal anti-inflammatory drugs, higher doses of aspirin), and hepatic impairment (increased drug exposure). In addition, the patient may experience clinical worsening of their depression symptoms, suicidality, and unusual changes in behavior because

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### VA PHARMACY BENEFITS MANAGEMENT SERVICES (PBM)

PBM maintains VA's national drug formulary, as well as promotes, optimizes, and assists VA practitioners with the safe and appropriate use of all medications.

### VA CENTER FOR MEDICATION SAFETY (VA MedSAFE)

VA MedSAFE performs pharmacovigilance activities; tracks adverse drug events (ADEs) using spontaneous and integrated databases; enhances education and communication of ADEs to the field; and promotes medication safety on a national level.

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NEWSWORTHY...

## from the pbm

- Eszopiclone (Lunesta): Lowered Dose Recommendations Due to Next-Day Impairment – 05/28/14 - [National PBM Bulletin](#)

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# from the fda

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## CENTRAL NERVOUS SYSTEM

### [FDA Drug Safety Communication: FDA warns of next-day impairment with sleep aid Lunesta \(eszopiclone\) and lowers recommended dose](#)

5/15/2014

Eszopiclone at higher doses, especially 3mg before bedtime, can cause next-day impairment of driving and other activities that require full attention/alertness, resulting in new lowered dosing recommendations. FDA approved a change to the product label, which includes the following dosing recommendations:

- *The recommended starting dose of eszopiclone has been lowered to 1 mg (from 2 mg).*
- *Dosing can be raised to 2 mg or 3 mg if clinically indicated.*
- *The total dose of eszopiclone should not exceed 3 mg, once each evening immediately before bedtime.*
- *Elderly patients and patients with hepatic impairment should not be prescribed doses of more than 2 mg.*
- *In some patients, the higher morning blood levels of eszopiclone following use of the 2 mg or 3 mg doses increase the risk of next-day impairment of driving and other activities that require full alertness.*
- *Patients taking a 3 mg dose of eszopiclone should avoid driving and other activities requiring acuity during the morning after use.*

See [National PBM Bulletin](#) and last issue ([Issue 5; Volume 4; May 2014](#)) for further details.

## CARDIOLOGY

### [FDA Drug Safety Communication: FDA study of Medicare patients finds risks lower for stroke and death but higher for gastrointestinal bleeding with Pradaxa \(dabigatran\) compared to warfarin](#)

5/13/2014 \*\*\*UPDATE FROM 11/02/2012\*\*\*

FDA recently completed a new study in more than 134,000 Medicare patients aged 65 years or older (37,500 person-years of follow-up) comparing blood thinners dabigatran (Pradaxa) to warfarin (Coumadin, Jantoven, and generics), for risk of ischemic stroke, intracranial hemorrhage, major gastrointestinal (GI) bleeding, myocardial infarction (MI), and death. Results showed a lower risk of ischemic stroke, intracranial hemorrhage, and death with dabigatran (Pradaxa) than with warfarin. The study also found an increased risk of major gastrointestinal bleeding with use of dabigatran (Pradaxa) as compared to warfarin. Data suggested similar risk for MI between the two drugs. This study's findings, with the exception of MI outcomes, are consistent with the clinical trial results from the Randomized Evaluation of Long-Term Anticoagulation Therapy (RE-LY) trial that supported FDA's approval of dabigatran (Pradaxa). (The RE-LY study showed an increased risk of MI observed with dabigatran [Pradaxa] compared to warfarin). These findings will not affect the current label or recommendations for use for dabigatran (Pradaxa).

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of insufficient drug therapy for their depression. On the converse, unintended use of Brintellix (vortioxetine) instead of Brilinta (ticagrelor) in a patient with ACS may put the patient at risk for a myocardial infarction, stent thrombosis, or death due to inadequate antiplatelet coverage. Furthermore, inadvertent use of Brintellix (vortioxetine) concomitantly and unknowingly with other serotonergic drugs, including triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, buspirone, tryptophan, and certain over-the-counter medications as well as drugs that may impair the metabolism of serotonin (i.e., monoamine oxidase inhibitors) may potentiate the risk for serotonin syndrome.

Brilinta (ticagrelor) and Brintellix (vortioxetine) share the same

first three letters as well as other trailing letters leading to the look-alike name error despite the difference in strengths, dosing schedules, and appearance of the formulations. Brilinta (ticagrelor) 90 mg is supplied as a round, biconvex, yellow, film-coated tablet marked with a "90" above "T" on one side. Brintellix (vortioxetine) is available as immediate-release, film-coated tablets in the following strengths:

- 5 mg: pink, almond shaped biconvex film coated tablet, debossed with "5" on one side and "TL" on the other side;
- 10 mg: yellow, almond shaped biconvex film coated tablet, debossed with "10" on one side and "TL" on the other side;
- 15 mg: orange, almond shaped biconvex film coated tablet,

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# Getting the most from our safety surveillance

## ATTENTION PHARMACISTS: NATIONAL MEDICATION USE EVALUATION (MUE) OPPORTUNITIES

VA MedSAFE offers different MUE process options for pharmacist involvement. Both options afford the advantage of providing sites with nationally designed MUEs on relevant issues within the VA system. While the nationally-administered route offers the benefit of full data analysis, the locally-administered alternative provides flexibility for sites to complete their own analysis at their own pace. Participation in either enables facilities to increase their awareness of various medication issues under evaluation in the VA system, improve medication use processes, and optimize patient outcomes while maintaining standards of care. MUE foci are determined at the national level and have included evaluations assessing large-scale therapeutic conversions, compliance with PBM Criteria for Use guidance documents, and adherence to evidence-based guidelines as set forth by various consensus panels. Examples of upcoming MUEs involve evaluation of antimicrobial agents and opioid therapy. For more information on future or ongoing MUEs and details on how to participate, please contact Muriel Burk at [Muriel.Burk@va.gov](mailto:Muriel.Burk@va.gov).

### MULTI-SITE MUES COORDINATED NATIONALLY (OPTION 1)

With this type of MUE, VA MedSAFE will:

- Provide participating sites with local unique identifiers consisting of the MUE cohort of interest.
- Establish a standardized data collection schemata of endpoint measures.
- Coordinate a uniform time line for participating sites to begin and end their data collection.
- Collate and analyze the raw patient data nationally after participating sites submit their information.
- Share final results of aggregate data.

Responsibilities of a participating site include:

- Obtaining local approval for the MUE from the appropriate designated governing body.
- Reviewing and abstracting relevant MUE data in accordance with VA privacy and information security policies.
- Adhering to central VA MedSAFE MUE protocol.
- Maintaining communication with VA MedSAFE for MUE-related questions or to follow-up on issues regarding data and its collection.
- Submitting completed chart review data within set timelines.
- Responding to follow-up questions/data-cleaning as necessary.

### INDIVIDUAL SITE MUES DESIGNED NATIONALLY (OPTION 2)

With this type of MUE, VA MedSAFE will:

- Provide interested sites with a ready-made MUE package including a protocol, data collection schemata, and results template.
- Collect final aggregate (non-identifiable) results from participating sites.

Responsibilities of a participating site include:

- Implementing the MUE locally using their own timeline (but within a broader established timeframe) using the templates provided by VA MedSAFE.
- Sharing final results and analyzed data with VA MedSAFE in aggregate.

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- debossed with “15” on one side and “TL” on the other side;
- 20 mg: red, almond shaped biconvex film coated tablet, debossed with “20” on one side and “TL” on the other side.

ISMP recommended the following steps to reduce future look-alike confusion with these similarly-named agents:

- Pharmacy should build software alerts to warn about possible look-alike name confusion due to similar spelling between Brilinta (ticagrelor) and Brintellix (vortioxetine);
- Providers should use both generic names and brand names when prescribing either Brilinta (ticagrelor) or Brintellix (vortioxetine); and
- Providers should list the indication when prescribing either Brilinta (ticagrelor) or Brintellix (vortioxetine).

Within the VA, if sites are using brand names of these agents in their drug file, then pharmacy can take the following steps inside the computerized drug-order entry system to reduce potential look-alike error with these orthographically similar names:

- Delete “brand” name from synonym field

in VistA pharmacy orderable item file #50.7 for these entries to force prescriber selection by generic name.

- Add a short descriptor (less than 74 characters) to “Display Restriction/Guidelines”. As blue line text, this descriptor (i.e., antiplatelet or antidepressant) displays as dialog and does not become part of order.
- Add brand name in parenthesis after generic name in VistA pharmacy orderable item file #50.7.

In addition, pharmacy should review their stock for Brilinta (ticagrelor) and Brintellix (vortioxetine), and ensure that a method is in place to distinguish between the two agents in order to avoid potential look-alike confusion (i.e., warning stickers/labels, separate product placement on shelves).

### REFERENCES:

1. Institute for Safe Medication Practices (ISMP). Similar drug names confused. *ISMP Medication Safety Alert! Acute Care* June 2014; 19 (12): 2-3.
2. BRILINTA (ticagrelor) product package insert. Wilmington, DE: AstraZeneca LP; December 2013.
3. BRINTELLIX (vortioxetine) product package insert. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; September 2013. ■