

# MEDICATION

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

# SAFETY IN SECONDS

## Helping to achieve safe medication use

### FDA APPROVES BRAND NAME CHANGE FOR ANTIDEPRESSANT DRUG BRINTELLIX (VORTIOXETINE) TO AVOID CONFUSION WITH ANTIPLATELET DRUG BRILINTA (TICAGRELOR)

FDA approved a brand name change for the antidepressant Brintellix (vortioxetine) to decrease the risk of look-alike/sound-alike (LA/SA) 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. However, during the transition period, older bottles displaying the previous brand name Brintellix as well as bottles with the new brand name Trintellix may both be seen in circulation because of the lag time associated with manufacturing. Trintellix tablets will look the same as the Brintellix tablets.

PBM previously addressed LA/SA brand name confusion between Brintellix (vortioxetine) and Brilinta (ticagrelor) 2 years ago in the [Issue 6; Volume 4; June](#)

[2014](#) issue of this newsletter, along with recommendations for considerations that pharmacy may take within the VA's computerized provider order entry system to reduce the potential for confusion with this look-alike name pair. PBM re-addressed the issue last year in the [Issue 7; Volume 5; July/August 2015](#) issue of this newsletter when FDA released a drug safety communication reporting multiple medication errors associated with this LA/SA brand name confusion. Continued reports of name confusion between the two medicines used for different indications prompted the FDA to work with Brintellix manufacturer Takeda Pharmaceuticals to change the drug's brand name.

During the transition to the new name change from Brintellix to Trintellix, FDA recommends that providers:

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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.

### EDITOR-IN-CHIEF

**Marie Sales, Pharm.D.**  
VA Pharmacy Benefits Management Services [PBM] & Center for Medication Safety [VA MedSAFE]; 1st Avenue—1 Block North of Cermak Road | Building 37; Room 139 | Hines, Illinois | 60141; [www.pbm.va.gov](http://www.pbm.va.gov)

### NEWSWORTHY...

## from the pbm

- Metformin Revised Warnings – 04/18/2016 - [National PBM Bulletin](#)
- Thyrogen® (thyrotropin alfa for injection) Recall Due to Glass Particulates – 04/01/2016 - [National PBM Patient Level Recall Communication](#)
- Look-Alike/Sound-Alike Confusing Name Pairs Specific to VA: UPDATED LINKS - [Cumulative VA LASA list 2015](#) ; [VA LASA list 2015](#)

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# from the fda

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## INFECTIOUS DISEASE

### [FDA to review study examining use of oral fluconazole \(Diflucan\) in pregnancy](#)

4/26/2016

FDA is now evaluating the results of a Danish study that shows a possible increased risk of miscarriage with the use of one or two doses of 150 mg oral fluconazole (Diflucan) for yeast infections. Until their review is complete, FDA recommends cautious prescribing of oral fluconazole during pregnancy:

- **Health care professionals** should be aware that the Centers for Disease Control and Prevention guidelines recommend only using topical antifungal products to treat pregnant women with vulvovaginal yeast infections, including for longer periods than usual if these infections persist or recur.
- **Patients** who are pregnant or actively trying to get pregnant should talk to their health care professionals about alternative treatment options for yeast infections.

The current FDA drug label for the antifungal agent fluconazole (Diflucan) states that data available from human studies do not suggest an increased risk of problems during pregnancy or abnormalities in developing babies when women receive a single 150 mg dose of oral fluconazole to treat vaginal yeast infections. However, repeated high doses of oral fluconazole (400-800 mg/day) taken by pregnant women have resulted in abnormalities at birth.

## ENDOCRINOLOGY

### [FDA revises warnings regarding use of the diabetes medicine metformin in certain patients with reduced kidney function](#)

4/8/2016

FDA recently reviewed evidence in the published medical literature and concluded that metformin may be safely used in patients with mild to moderate renal impairment. New labeling changes will reflect this information. Label revisions will also recommend determining kidney function using glomerular filtration rate (instead of blood creatinine clearance) since it incorporates patient's age, gender, race, and/or weight.

FDA recommendations include :

- *Before starting metformin, obtain the patient's eGFR.*
- *Metformin is contraindicated in patients with an eGFR below 30 mL/minute/1.73 m<sup>2</sup>.*
- *Starting metformin in patients with an eGFR between 30-45 mL/minute/1.73 m<sup>2</sup> is not recommended.*
- *Obtain an eGFR at least annually in all patients taking metformin. In patients at increased risk for the development of renal impairment such as the elderly, renal function should be assessed more frequently.*
- *In patients taking metformin whose eGFR later falls below 45 mL/minute/1.73 m<sup>2</sup>, assess the benefits and risks of continuing treatment. Discontinue metformin if the patient's eGFR later falls below 30 mL/minute/1.73 m<sup>2</sup>.*
- *Discontinue metformin at the time of or before an iodinated contrast imaging procedure in patients with an eGFR between 30 and 60 mL/minute/1.73 m<sup>2</sup>; in patients with a history of liver disease, alcoholism, or heart failure; or in patients who will be administered intra-arterial iodinated contrast. Re-evaluate eGFR 48 hours after the imaging procedure; restart metformin if renal function is stable.*

For additional details, please see the [National PBM Bulletin](#) issued by PBM last month.

### [FDA adds warnings about heart failure risk to labels of type 2 diabetes medicines containing saxagliptin and alogliptin](#)

4/5/2016

FDA reports that type 2 diabetes medicines containing saxagliptin and alogliptin may increase the risk of heart failure (especially in patients who already have heart or kidney disease) and adds new warnings to the drug labels. This is based on two large clinical trials conducted in patients with type 2 diabetes mellitus and heart disease:

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# from the fda (continued from page 2)

- The Saxagliptin Assessment of Vascular Outcomes Recorded in Patients with Diabetes Mellitus (SAVOR) trial was a large, prospective, multicenter, randomized, double-blind, placebo-controlled trial conducted in 16,492 patients.
  - ◇ Patients were followed for a median duration of 2 years.
  - ◇ More patients randomized to the saxagliptin group (289/8280, 3.5%) were hospitalized for heart failure compared to patients randomized to placebo (228/8212, 2.8%) [estimated hazard ratio: 1.27; 95% confidence interval: 1.07, 1.51].
  - ◇ Identified risk factors in patients hospitalized for heart failure included a history of heart failure or renal impairment.
- The Examination of Cardiovascular Outcomes with Alogliptin versus Standard of Care in Patients with Type 2 Diabetes Mellitus and Acute Coronary Syndrome (EXAMINE) trial was a multicenter, randomized, double-blind, placebo-controlled trial that enrolled 5,380 patients.
  - ◇ Patients were followed for 1.5 years on average.
  - ◇ More patients randomized to the alogliptin group (106/2701, 3.9%) experienced at least one hospitalization for heart failure compared to patients randomized to placebo (89/2679, 3.3%).

FDA recommends that healthcare professionals:

- Consider the risk and benefits of saxagliptin or alogliptin prior to initiating treatment in patients at a higher risk for heart failure.
- Observe patients receiving saxagliptin or alogliptin for signs and symptoms of heart failure.
  - ◇ If heart failure develops, consider discontinuing the drug and monitor diabetes control.
  - ◇ If blood sugar level is not well-controlled with a patient's current treatment, other diabetes medicines may be required.
- Instruct patients about :
  - ◇ Signs and symptoms of heart failure, such as:
    - ⇒ Unusual shortness of breath during daily activities
    - ⇒ Trouble breathing when lying down
    - ⇒ Tiredness, weakness, or fatigue
    - ⇒ Weight gain with swelling in the ankles, feet, legs, or stomach
  - ◇ Not stopping their saxagliptin or alogliptin medicine without first talking to their health care professional.
  - ◇ Contacting their health care professional right away if they develop signs and symptoms of heart failure when taking saxagliptin or alogliptin.

## Getting the most from our safety surveillance

### LOOK-ALIKE SOUND-ALIKE CONSIDERATIONS

One local VA medical center (VAMC) reported two look-alike/sound-alike (LA/SA) scenarios that involved brand name mix-ups at the transition of care, during admission.

On one occasion, name pair confusion occurred between Protonix® and Prothrombin Complex. Although the patient was receiving pantoprazole as an outpatient, the admitting provider may have thought of the brand name "Protonix®" and inadvertently ordered the wrong drug (Prothrombin complex) instead due to orthographic and phonetic similarities. The pharmacist

caught the error while processing the order, and the patient never received prothrombin complex.

Another incident transpired between Lamisil® and lamivudine. During a prior hospitalization, a patient was diagnosed with nail dermatophytosis, but not prescribed treatment or medication at that time. Upon this admission, the nurse practitioner may have thought to order Lamisil® with the nail dermatophytosis diagnosis and selected lamivudine in error from the drop down menu due to similar spelling. As the pharmacist conducted a

# Getting the most from our safety surveillance

## LOOK-ALIKE SOUND-ALIKE CONSIDERATIONS

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discharge medication review, no indication could be found for lamivudine; and at that time it was discovered that the patient was mistakenly prescribed lamivudine in lieu of the antifungal.

These cases serve to show that:

- Brand names are not entirely free from risk of a LA/SA mix-up in VA even though it is a predominantly generic-name based environment. This could possibly be due to:
  - ◆ VAMCs with a university affiliate where providers share time at both facilities may think in terms of “brand”;
  - ◆ Rotating residents may share the same predisposition;
  - ◆ Influence of marketing media;
- Transition of care during a hospital admission may be sus-

ceptible to LA/SA mix-ups, even for brand names;

- Medication reconciliation is equally important both at times of admission and at discharge.

For more information on Look-Alike/Sound-Alike confusing name pairs specific to VA, visit:

- [Cumulative VA LASA list 2015](#) ;
- [VA LASA list 2015](#)

We would like to thank the following VISNs for contributing to the 2015 VA LASA report (which serves as the basis for the above lists): VISNs 6, 8, 9, 16, and 20.

**REFERENCE:**  
Internal Data

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### FDA APPROVES BRAND NAME CHANGE FOR ANTIDEPRESSANT DRUG BRINTELLIX (VORTIOXETINE) TO AVOID CONFUSION WITH ANTIPLATELET DRUG BRILINTA (TICAGRELOR)

*(continued from page 1)*

- Should check carefully to make sure they have prescribed or dispensed the correct medicine.
- Reduce the risk of name confusion by entering the generic name of the medication they are ordering and include the indication for use on the prescription.
- Instruct patients that Trintellix tablets will look the same as the Brintellix tablets.

- Be aware that Trintellix will have a new National Drug Code (NDC) number (for individuals responsible for ordering and stocking the medicine).

**REFERENCE:**

FDA Drug Safety Communication: FDA approves brand name change for anti-depressant drug Brintellix (vortioxetine) to avoid confusion with antiplatelet drug Brilinta (ticagrelor). <http://www.fda.gov/Drugs/DrugSafety/ucm497942.htm> . ■