

MEDICATION SAFETY IN SECONDS

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

Helping to achieve safe medication use

DABIGATRAN (PRADAXA) CAPSULES: DO NOT BREAK, OPEN, OR CHEW BEFORE ADMINISTRATION

The Institute for Safe Medication Practices (ISMP) received a report from a hospital regarding an adverse drug event that occurred as a result of inappropriate administration of dabigatran (Pradaxa) to a patient. A patient presented with hematemesis to a hospital's Emergency Department due to health care staff at a separate care facility opening the patient's dabigatran capsules and sprinkling the contents onto the patient's food for ease of administration. This practice is not recommended because doing so increases drug absorption and anti-coagulant activity, putting the patient at an increased risk for bleeding.

Health care practitioners should be reminded of the following:

- Product labelling information specifically states that *"The oral bioavailability of dabigatran etexilate increases by 75% when the pellets are taken without the capsule shell compared to the intact capsule formulation. PRADAXA capsules should therefore not be broken,*

chewed, or opened before administration."

- Dabigatran (Pradaxa) appears on the DO NOT CRUSH list available on ISMP's website (www.ismp.org/Tools/DoNotCrush.pdf).
- VA guidance put forth by the National Pharmacy Benefits Management Services (PBM) also warns that dabigatran capsules should not be opened, broken, or chewed. Further details can be found in the [Dabigatran Drug Monograph](#) located on the VA PBM website (<http://www.pbm.va.gov/>).

To date, the VA Adverse Drug Event Reporting System (VA ADERS) has not received any reports of similar inappropriate instances of opening dabigatran capsules prior to administration within VA's health care system.

REFERENCES

Institute for Safe Medication Practices (ISMP). Safety Briefs: Don't open Pradaxa capsules. *ISMP Medication Safety Alert! Acute Care*. February 2015; 20 (3): 2-3. ■

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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



from ismp

FARXIGA (DAPAGLIFLOZIN) AND FETZIMA (LEVOMILNACIPRAN): LOOK-ALIKE/SOUND-ALIKE NAME CONFUSION

The Institute for Safe Medication Practices (ISMP) reports 5 medication errors submitted to the Food and Drug Administration (FDA) that involved look-alike/ sound-alike (LA/SA) name confusion between 2 medications: Farxiga (dapagliflozin), an antidiabetic agent, and Fetzima (levomilnacipran), an antidepressant. FDA attributes the errors to orthographic and phonetic similarities, where both drugs begin with the letter “F” and end with the letter “A” as well as carry the same number of letters and syllables. Another contributing factor is that both drugs were approved and introduced into the market at roughly around the same time, with Fetzima (levomilnacipran) approved in July 2013 and Farxiga (dapagliflozin) approved 6 months later in January 2014. Additionally, product packaging for both agents utilize a white label and display the brand name in red font, lending to possible confusion. (Figure 1)

The potential for harm can occur with inadvertent mix-up of these drugs. In fact, Farxiga (dapagliflozin), as an antidiabetic agent, falls within the class of oral hypoglycemic agents listed as part of ISMP’s list of High-Alert Medications that bear a heightened risk of causing significant patient harm when they are used in error. A patient mistakenly given Farxiga (dapagliflozin) instead of Fetzima (levomilnacipran) may be at risk for low blood glucose levels while not getting the therapeutic dose of their antidepressant to manage their mood. On the converse, a patient who receives Fetzima (levomilnacipran) in error instead of Farxiga (dapagliflozin) may be at risk for inadequate control of their glucose levels and may display signs and symptoms of hyperglycemia.

ISMP recommends to consider:

- Adding computer alerts to verify the indication for these medications ;
- Including the indication with orders or prescriptions;
- Counseling all patients before dispensing these drugs to confirm the indication.

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 the “brand” name from the synonym field in the VistA pharmacy orderable item file #50.7 for these entries in order to force prescriber selection by generic name.
- Add a short descriptor (less than 74 characters) to “Display Restriction/Guidelines”, also known as DRUG TEXT. As blue line text, this descriptor (i.e., antidiabetic or antidepressant) displays on the medication order dialog and does not have to become part of the order itself.
- Add the brand name in parentheses after the generic name in the VistA pharmacy orderable item file #50.7.

In addition, pharmacy should review their stock for Farxiga (dapagliflozin) and Fetzima (levomilnacipran) 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).

Figure 1. Similarities in name and label appearance may contribute to look-alike confusion between these medications.



REFERENCE:

Institute for Safe Medication Practices (ISMP). Safety Brief: Farxiga and Fetzima mix-ups. *ISMP Medication Safety Alert! Acute Care* January 2015; 20 (1): 3-4. ■

Getting the most from our safety surveillance

LOOK-ALIKE ERRORS WITH BAXTER IRRIGATION PRODUCTS PROMPTS LABEL CHANGES

Baxter Healthcare received reports of 0.25% Acetic Acid for Irrigation being used in error instead of another intended Baxter irrigation product according to a Safety Alert released by the manufacturer in December 2014. Similar label appearance may have contributed to the errors, prompting the manufacturer to update product labeling for 0.25% Acetic Acid for Irrigation (Product Code = 2F7184, Lot # = ALL) to better differentiate it from that of Sterile Water for Irrigation and 0.9% Sodium Chloride for Irrigation.

Figures 1, 2, and 3 show that 0.25% Acetic Acid for Irrigation, Sterile Water for Irrigation, and 0.9% Sodium Chloride for Irrigation are packaged in similar-looking 1000 mL clear plastic bottles. All bottles have translucent blue safety seals on the caps. The placement, font style, and color are similar for the volume, manufacturer's name, expiration date, and product description. There are two points of distinction among the labels of these three solutions. First, the color of the font is grey for the Acetic Acid product name while the font is light blue for the Sterile Water product name and red for the Sodium Chloride product name. Second, the shading block for the expiration dates is grey for the Acetic Acid product name while it appears as light blue

for the Sterile Water product name and red for the Sodium Chloride product name.

VA PBM and MedSAFE previously issued a [National PBM Bulletin](#) in 2008 that addressed a look-alike mix-up that occurred between 0.25% Acetic Acid and Sterile Water for Irrigation at one VAMC. In this instance, the mix-up was caught and no serious adverse outcomes were reported. However, the potential for harm exists if the error of using the wrong product is made, and Baxter has received reports of adverse events related to this issue. While implementation of a label change by the manufacturer is pending, recommendations to reduce the risk of future look-alike error include:

1. Pharmacy must alert SPD and nursing staff of potential look-alike confusion between 0.25% Acetic Acid Irrigation other irrigations products, such as Sterile Water for Irrigation or 0.9% Sodium Chloride for Irrigation.
2. Pharmacy should assist SPD in adding warning stickers/labels on bottles of 0.25% Acetic Acid.
3. Unused bottles of Acetic Acid must be returned to SPD when not on order for a particular patient. ■



Figure 1. 0.25% Acetic Acid for Irrigation, USP, 1000 mL Plastic Pour Bottle.



Figure 2. 0.9% Sodium Chloride for Irrigation, USP, 1000 mL Plastic Pour Bottle.



Figure 3. Sterile Water for Irrigation, USP, 1000 mL Plastic Pour Bottle.