

MEDICATION

A MONTHLY PUBLICATION FROM VA MEDSAFE:
VA'S COMPREHENSIVE PHARMACOVIGILANCE CENTER**SAFETY IN SECONDS**

Helping to achieve safe medication use

PHENYLEPHRINE (VAZCULEP) AND NEOSTIGMINE (BLOXIVERZ): POTENTIAL LOOK-ALIKE CONFUSION

The Institute for Safe Medication Practices (ISMP) has received 8 practitioner reports concerning possible confusion due to look-alike packaging between neostigmine (Bloxiverz) 10mg/10mL (1mg/mL) and phenylephrine (Vazculep) 50mg/5mL (10mg/mL) manufactured by Eclat Pharmaceuticals (Figure 1, page 4). In several hospitals, vials or cartons of neostigmine (Bloxiverz) 10mg/10mL were intermingled with phenylephrine (Vazculep) 50mg/5mL vials or cartons. Five of the eight reports involved "close calls", where the wrong drug was used during sterile compounding, but the error was identified during the checking process so the incorrect product did not reach the patient.

Since these agents are primarily used in surgical settings, there is potential for serious

adverse drug events to occur if the wrong drug is used. Erroneous administration of phenylephrine (Vazculep) instead of neostigmine (Bloxiverz) can result in overdose of phenylephrine, possibly leading to cardiac arrest, or extreme hypertension and a cerebral vascular accident, or death. On the other hand, if the patient mistakenly receives neostigmine (Bloxiverz) instead of phenylephrine (Vazculep), bradycardia, hypotension, or tachycardia may ensue, as well as reversal of paralytics.

ISMP recommends that health care organizations using these products take the following steps to prevent mix-ups between these agents:

- Store phenylephrine (Vazculep) and neostigmine (Bloxiverz) separately in both long-term and short-term storage

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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

NEWSWORTHY...

from the pbm

- SGLT2 Inhibitors and Potential Risk for Acidosis – 05/22/15 - [National PBM Bulletin](#)
- Ketorolac Recall Due to Particles in Glass Vial – 05/04/15 - [National PBM Patient Level Recall Communication](#)

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from the fda

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INFECTIOUS DISEASE

[FDA cautions about dose confusion and medication errors for antibacterial drug Zerbaxa \(ceftolozane and tazobactam\)](#)

5/20/2015

Seven cases of medication errors for Zerbaxa (ceftolozane and tazobactam) have been reported to the FDA since its approval in December 2014. These errors involved incorrect doses due to confusion about the drug strength displayed on the vial and carton labeling since the initially approved vial label reflected each individual active ingredient (e.g. 1 g/0.5 g) (Figure 1); however, the product is dosed based on the sum of these ingredients (e.g. 1.5 g). In all cases, a provider prescribed a total dose of either 1.5 grams or 3 grams (representing the sum of the two ingredients) but the dose to be administered was calculated based on the amount of ceftolozane in the Zerbaxa vial (listed as 1 gram), resulting in a 50% overdose. Four of the seven reported cases resulted in an actual error where the patient did receive a wrong dose, although no adverse events were reported. In the other three cases, pharmacists identified the error before the drug was administered to the patients. To prevent future medication errors, the strength on the drug labeling has been revised to reflect the sum of the two active ingredients: 1.5 grams equivalent to ceftolozane 1 gram and tazobactam 0.5 gram (Figure 2).

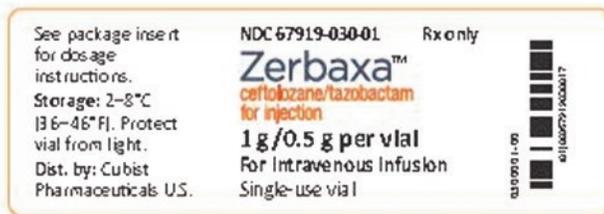


Figure 1. Initial approved label led to dosing confusion as the drug strength is displayed for each individual active ingredient instead of as a sum of the ingredients as in other approved beta-lactam/beta-lactamases antibacterial drug products.

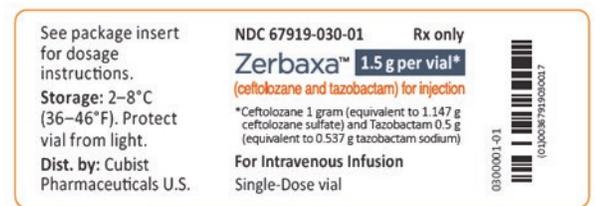


Figure 2. Revised label now lists drug strength as a sum of the active ingredients.

ENDOCRINOLOGY

[FDA warns that SGLT2 inhibitors for diabetes may result in high anion gap metabolic acidosis](#)

5/15/2015

FDA is investigating postmarketing reports of sodium-glucose cotransporter-2 (SGLT2) inhibitor use and potential development of a high anion gap metabolic acidosis accompanied by elevation in urine or serum ketones and will determine if changes are needed in the labeling for this class of drugs. For more details, please see the [National PBM Bulletin](#) issued this month. FDA recommends that health care providers:

- Be aware of the possible development of a high anion gap metabolic acidosis accompanied by elevation in urine or serum ketones associated with the use of SGLT2 inhibitors, even if glucose levels are not very high as is typical for DKA.
- Evaluate any presence of acidosis, including ketoacidosis, for appropriate action:
 - discontinue SGLT2 inhibitors if acidosis is confirmed;
 - correct the acidosis and monitor glucose levels;
 - treat and correct factors that may have precipitated or contributed to the metabolic acidosis.
- Educate patients and caregivers of the signs and symptoms of metabolic acidosis, such as tachypnea or hyperventilation, anorexia, abdominal pain, nausea, vomiting, lethargy, or mental status changes, and instruct them to seek medical attention immediately if these symptoms occur.

Getting the most from our safety surveillance

DABIGATRAN AND DABRAFENIB: LOOK-ALIKE / SOUND-ALIKE CONFUSION

One local medical center reported look-alike/sound-alike (LA/SA) confusion between dabigatran, an oral anticoagulant, and dabrafenib, an oral chemotherapeutic agent. A provider entered a non-formulary consult for the anticoagulant DABIGATRAN 150MG CAP twice daily, which was approved. However, when the corresponding medication order was entered, another medication, DABRAFENIB 75MG CAP-2 caps twice daily, an antineoplastic agent, was selected. Fortunately, the error was caught and the patient did not receive the wrong medication.

Contributing factors to the LA/SA confusion include:

- Orthographic and phonetic similarities in names;
- Both have a 150mg selection for dose in the computerized provider order entry system;
- Both agents share similar dosing schedules of 150mg orally taken twice daily.

If the patient mistakenly receives dabrafenib instead of dabigatran, they may not receive adequate anticoagulation, putting them at risk for emboli formation and/or stroke. If the error occurred in the reverse and a patient inadvertently receives dabigatran instead of dabrafenib, they may experience suboptimal response rates for treating their unresectable and/or metastatic melanoma while the potential for bleeding events may increase in at-risk patients.

This local site has explored potential drug file changes to help prevent future LA/SA confusion with this drug pair. Actions

taken on drug order selection alerts include:

- Using mixed case (tallMAN) lettering for Pharmacy Orderable item DABRAFENIB (Figure 1);
- Adding a short descriptor (less than 74 characters) cautioning of Look-Alike/Sound-Alike potential in blue text (Display Restrictions/Guidelines) to DABRAFENIB (Figure 2);
- Quantity Dispensed message also contains a caution to confirm drug selection (Figure 2).

Additional recommendations include:

- Consider duplicating the mixed case (tallMAN) lettering and orderable item text alert to a LA/SA warning for dabigatran as well in the event that the error takes place in reverse.
- Consider adding a default indication for each of the drugs to further distinguish between the two agents.
- In addition, pharmacy should review their stock 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. Local site report.
2. Pradaxa® (dabigatran) product package insert. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; January 2015.
3. Tafinlar® (dabrafenib) product package insert. Research Triangle Park, NC: GlaxoSmithKline; January 2014.

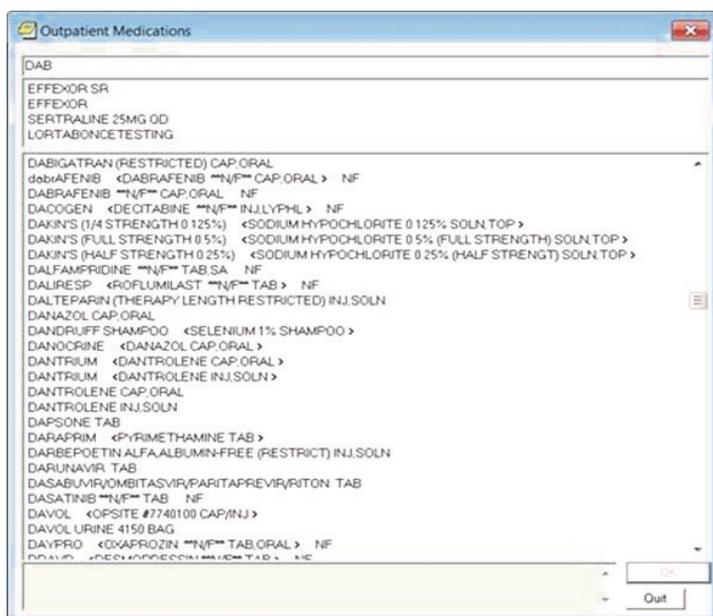


Figure 1. Mixed case (tallMAN) lettering for dabrafenib was implemented at one local facility to help prevent LA/SA confusion between dabrafenib and dabigatran while ordering in the computerized provider order entry system.

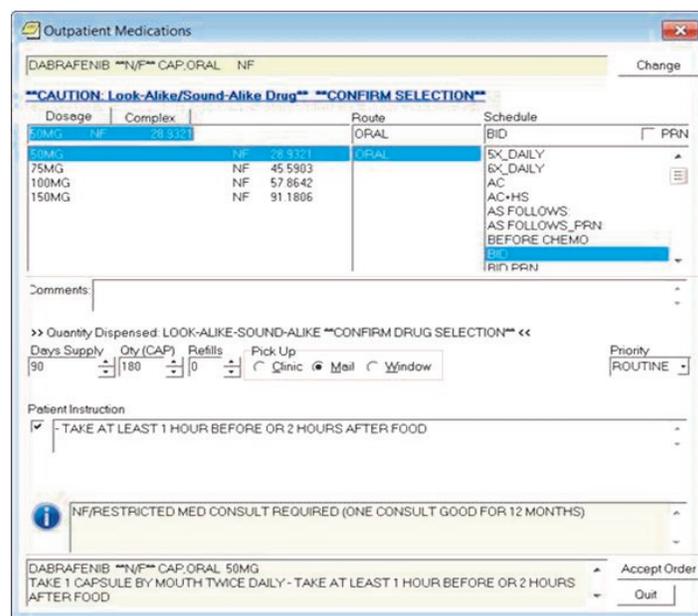


Figure 2. Blue text (Display Restrictions/Guidelines) at the top of the order screen alerts providers about possible LA/SA confusion between dabrafenib and dabigatran, while a second message in the "Quantity Dispensed" section in the middle of the order screen reiterates the caution.

Helping to achieve safe medication use

PHENYLEPHRINE (VAZCULEP) AND NEOSTIGMINE (BLOXIVERZ): POTENTIAL LOOK-ALIKE CONFUSION

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areas.

- Alert staff to the potential risk for confusion between phenylephrine (Vazculep) and neostigmine (Bloxiverz).
- Verify product selection during inventory management, and prior to dispensing or drug preparation.
- Eliminate purchasing bulk packages of phenylephrine (Vazculep). If purchased and used, then storage should be limited to pharmacies.
- Dilute phenylephrine (Vazculep) prior to administration for bolus doses.

ISMP has notified the manufacturer and FDA of these concerns.

REFERENCES

NAN ALERT. Warning! Potentially dangerous confusion between Bloxiverz (neostigmine) injection and Vazculep (phenylephrine) injection. National Coordinating Council on Medication Error Reporting and Prevention (NCCMERP): March 23, 2015. ■



Figure 1. Similar packaging has led to look-alike confusion between neostigmine (Bloxiverz) 10mg/10mL (1mg/ml) and phenylephrine (Vazculep) 50mg/5mL (10mg/mL).