This alert is based on information from the National Medication Errors Reporting Program operated by the Institute for Safe Medication Practices.

March 23, 2015

Warning! Potentially dangerous confusion between Bloxiverz (neostigmine) injection and Vazculep (phenylephrine) injection

ISMP is alerting hospitals, ambulatory surgical centers, and anesthesia professionals about the potential for dangerous mix-ups between two relatively new presentations of older medications, neostigmine injection and phenylephrine injection.

Eclat Pharmaceuticals is currently manufacturing **BLOXIVERZ** (neostigmine) and **VAZCULEP** (phenylephrine). Bloxiverz became the first FDA-approved neostigmine product in 2013. It is a chlolinesterase inhibitor indicated for the **REVERSAL** of non-depolarizing neuromuscular blockade after surgery. Vazculep is a phenylephrine injection product approved in 2014 for treatment of clinically important hypotension resulting primarily from vasodilation in the setting of anesthesia.

Figure 1. Mix-ups between Bloxiverz and Vazculep have occurred at hospitals around the US.

The company is marketing the following products and container sizes:

Bloxiverz (neostigmine 0.5 mg/mL and 1 mg/mL)

- 5 mg/10 mL vial
- 10 mg/10 mL vial

Vazculep (phenylephrine 10 mg/mL)

- 10 mg/mL vial
- 50 mg/5 mL pharmacy bulk package
- 100 mg/10 mL pharmacy bulk package

The pharmacy bulk packages are intended for use in the pharmacy during sterile compounding of infusions.

In the past 3 months, ISMP has received 8 practitioner reports expressing concern about look-alike packaging of Bloxiverz 10 mg/10 mL (1 mg/mL) and Vazculep 50 mg/5 mL (10 mg/mL). The vials and outer cartons look similar in size, color, and design (**Figure 1**). Several hospitals have reported that vials or cartons of the 10 mg Bloxiverz product were found mixed in with Vazculep 50 mg/5 mL (10 mg/mL) vials or cartons. Of the 8 reports, five were close calls in which the wrong product was actually used during sterile compounding. Fortunately, in each reported case, the error was identified during an independent check by a second person. If the wrong drug reached the patient, it could result in a serious adverse drug event, and thus, this national alert is urgent.

Bloxiverz is given by intravenous push as a weight-based dose of 0.03 to 0.07 mg/kg, up to a maximum of 5 mg. For a 70 kg person at the maximum dose of 0.07 mg/kg, the dose would equate to approximately 5 mg, or 5 mL of the 10 mg/10 mL (1 mg/mL) concentration. The recommended initial bolus dose of Vazculep is 40 to 100 mcg administered by intravenous bolus for hypotension during anesthesia, or 100 to 500 mcg by

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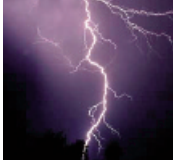

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intravenous bolus for hypotension associated with shock. If someone inadvertently has a Vazculep vial in hand instead of Bloxiverz, and draws up 5 mL (50 mg) of phenylephrine injection, this would lead to a 100-fold overdose of phenylephrine if based on the highest dose recommended for a patient in shock (500 mcg), or a 1,250-fold overdose of phenylephrine if based on the low range of the recommended dose for a patient with hypotension during anesthesia (40 mcg). That much phenylephrine could cause cardiac arrest, or extreme hypertension and a cerebral vascular accident or death.

If Vazculep is ordered for hypotension, but Bloxiverz is administered in error, the drug by itself can cause bradycardia, hypotension, or tachycardia. Patients who are receiving paralytics might experience a reversal of effects. To complicate the matter, staff may sometimes unknowingly invite a problem by requesting a bag of "neo" for infusion (referring to phenylephrine by a previous brand name **NEO-SYNEPHRINE**), which could be confused with neostigmine if staff are unfamiliar with the formerly available Neo-Synephrine brand of phenylephrine injection.

We strongly recommend that healthcare organizations using these products take immediate steps to safeguard against mix-ups. Consider the following:

- **Store separately.** It is possible that the letters N and P, being close alphabetically, may put these drugs in close proximity to one another on a shelf or in an anesthesia cart or emergency box, thereby increasing the risk of choosing the wrong product. To prevent mix-ups, keep supplies of these drugs widely separated in both short- and long-term storage areas.

- **Increase awareness.** Alert staff, especially operating room and anesthesia staff, to the potential risk of confusion between the two drugs.

- **Verify product selection.** Barcode scanning of containers during inventory management and prior to dispensing or drug preparation would help to prevent mix-ups, as would independent double-check systems when preparation is accomplished.

- **Eliminate or limit access.** If at all possible, do not purchase the pharmacy bulk packages of phenylephrine. If purchased and used, storage should be limited to pharmacies. The pharmacy bulk packages of phenylephrine injection contain many single doses or may be used to prepare phenylephrine infusions. The contents are intended for use only in pharmacy admixture programs.

- **Dilute prior to injection.** For bolus doses, phenylephrine injection must be diluted prior to administration.

We have communicated information about the error reports to Eclat Pharmaceuticals. We hope the manufacturer will revise its container labels as soon as possible to reduce the risk of errors. FDA is aware of this alert and the above concerns.

The National Alert Network **(NAN)** is a coalition of members of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). The network, in cooperation with the Institute for Safe Medication Practices (ISMP) and the American Society of Health-System Pharmacists (ASHP), distributes NAN Alerts to warn healthcare providers of the risk for medication errors that have caused or may cause serious harm or death. NCC MERP, ISMP, and ASHP encourage the sharing and reporting of medication errors both nationally and locally, so that lessons learned can be used to increase the safety of the medication use system.