

SITUATION:

A recent change in manufacturer B. Braun's packaging of potassium chloride for injection concentrate (2 mEq/mL) could cause it to be mistaken for an IV infusion bag. Previously B. Braun packaged potassium chloride for injection concentrate in a 250 mL glass bottle with a hanger. The product is now packaged in a 250 mL EXCEL container plastic bag with blue and red labeling and a blocked medication port.

This is serious safety concern since the potassium chloride for injection in the bag is highly concentrated and can stop a patient's heart if accidentally administered undiluted, resulting in a fatal outcome.

BACKGROUND:

Potassium chloride for injection concentrate ((2 mEq/mL) is a bulk packaged product to be used only in a pharmacy admixture service where it restricted to the preparation of admixtures for intravenous (IV) infusions.

Manufacturer B. Braun decommissioned their glass manufacturing line in the first quarter of 2022. As a result, they had to change their packaging of potassium chloride for injection and they chose to use a 250 mL EXCEL container plastic bag.

ASSESSMENT:

B. Braun and other companies' IV infusion bags such as sterile water for injection, premixed heparin, premixed potassium in chloride in 5% dextrose, hypertonic sodium chloride injection, or **HESPAN** (hetastarch) are labeled with similar blue and red print. They look very similar to plastic bags of potassium chloride for injection concentrate when removed from their overwrap and placed on a counter.

RECOMMENDATION:

If you elect to use the new potassium chloride for injection concentrate plastic bag containers instead of potassium chloride for injection concentrate vials in your IV admixture area, it is crucial to ensure that proper steps are taken to eliminate any confusion and prevent a fatal medication error.

#1. Ensure that only the pharmacy can purchase, store, and utilize this product.

Pharmacy must have processes in place to ensure the product is **never** distributed to any area outside of the pharmacy.

- a. Central supply and materials management staff, as well as clinics and other outpatient locations, should be prohibited from purchasing this product from wholesalers or other sources.
- b. The manufacturer has labeled the shipping case, "Pharmacy Bulk Package. For Pharmacy Use Only."

#2. After purchase and upon receipt of the potassium chloride for injection concentrate bags, pharmacy staff should

- a. immediately open the case and affix large, bold, auxiliary warning labels to the overwrap on both sides of all bags. While the manufacturer is currently including an auxiliary warning label to be affixed by staff, we recommend that pharmacy create additional labels so that warnings can be applied to both sides of the container.
- b. store all bags in their overwrap in the original open case and affix a warning to the case that states, "**For Pharmacy use ONLY**—Contains potassium chloride for injection concentrate."
- c. when ready to use, remove the overwrap and affix warning labels to both sides of the bag.

#3. Proper barcode scanning is imperative when using this product to prepare compounded sterile preparations (CSPs).

- a. If the white barcodes on these infusion bags are difficult to scan, placing the bag over a dark background may help.
- b. Establish an independent double check when the barcode will

not scan prior to bypassing this step.

- c. Identify any containers that might inadvertently be potassium chloride for injection concentrate, all premixed medications in IV bags that have been removed from their shipping cartons should be scanned before being used or dispensed.