

May 17, 2022



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

Potassium chloride for injection concentrate in EXCEL plastic bags



B. Braun recently announced a new presentation of potassium chloride for injection concentrate (2 mEq/mL) in a 250 mL EXCEL container plastic bag with blue and red labeling (www.ismp.org/ext/901), and a blocked medication port. The 250 mL product is a pharmacy bulk package and should only be used in a pharmacy admixture service where it is restricted to the preparation of admixtures for intravenous (IV) infusions. Until now, B. Braun has supplied potassium chloride for injection concentrate in a 250 mL glass bottle with a hanger and has been the only company in recent years to provide a 250 mL glass bottle presentation. However, the product needs to be changed to a different type of container because B. Braun's glass manufacturing line was decommissioned in the first quarter of 2022. In addition, the current shortage of potassium chloride for injection concentrate in all forms (e.g., plastic vials, glass bottles) has resulted in B. Braun's decision to use 250 mL plastic bags to continue to distribute this product.

ISMP has received several communications from pharmacists and pharmacy technicians who are concerned about the potential risk for this product's presentation to be mistaken for other B. Braun or another companies' IV infusion bags. Several are labeled with similar blue and red print, such as sterile water for injection, or premixed heparin, premixed potassium chloride in 5% dextrose injection, hypertonic sodium chloride injection, or **HESPAN** (hetastarch), which may look remarkably like plastic bags of potassium chloride for injection concentrate when removed from their overwrap and placed on a counter. 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.

There have been incidents in the past in which potassium chloride for injection concentrate in 250 mL bulk glass containers from other manufacturers (Abbott and Baxter) were involved in serious medication errors. In one report on file at the US Food and Drug Administration (FDA), a bulk package was accidentally infused directly into a patient's IV line, which proved fatal. In another case, a glass 250 mL bulk package of potassium chloride for injection concentrate was accidentally confused with a glass 250 mL container of dextrose 5% injection. The potassium chloride for injection concentrate was then used as a diluent for preparing multiple heparin 1 unit/mL syringes intended for neonatal umbilical lines, which led to the deaths of three infants.¹ Since there have been documented errors with look-alike glass containers, there is reason to believe that look-alike errors could also happen with pharmacy bulk packages of potassium chloride for injection concentrate in plastic containers. It should be noted that since these incidents, USP added a requirement for the cap of the glass container and the overseal of the cap to be black and bear the words: "Must Be Diluted." However, there is no cap or overseal used with plastic bags.

This alert is intended to bring immediate attention to this issue. For those who elect to use the new potassium chloride for injection concentrate plastic bag containers instead of potassium chloride for injection concentrate vials in their IV admixture area, it is crucial to ensure that proper steps are taken to eliminate any confusion. Organizations deciding to utilize this product should take the following steps to prevent potentially fatal medication errors:

- **Ensure that only the pharmacy can purchase, store, and utilize this product.** Pharmacy must have

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processes in place to ensure the product is **never** distributed to any area outside of the pharmacy. 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. The manufacturer has labeled the shipping case, “Pharmacy Bulk Package. For Pharmacy Use Only.”

- **After purchase and upon receipt of the potassium chloride for injection concentrate bags, pharmacy staff should 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 (**Figure 1**) to be affixed by staff, we recommend that pharmacy create additional labels so that warnings can be applied to both sides of the container. 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.” Additionally, when ready to use, remove the overwrap and affix warning labels to both sides of the bag.
- **Proper barcode scanning is imperative when using this product** to prepare compounded sterile preparations (CSPs). If the white barcodes on these infusion bags are difficult to scan, placing the bag over a dark background may help. Establish an independent double check when the barcode will not scan prior to bypassing this step. In addition, to 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.



Figure 1. Potassium chloride for injection concentrate auxiliary warning labels provided by the manufacturer.

ISMP is in communication with B. Braun, and dialog is underway about additional ways to enhance the proper identification of this product to reduce the potential for product confusion.

Reference

1. Cohen MR, Foss MM, Bock NJ. Potassium chloride injection mix-up. *Am J Hosp Pharm.* 1990;47(11):2457-8.



The National Alert Network (NAN) is a coalition of members from 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 about the risk of medication errors that have caused or may cause serious harm or death, or to warn them about new findings that could cause harm and/or are being reported with unusual frequency. 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.