Safety Notice 021/21

Safety risks due to new labelling on the outer carton packaging of intravenous potassium chloride ampoules

10 September 2021

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Director, Regulation and Compliance Unit

Action required by:

- Chief Executives
- Directors of Clinical Governance

We recommend you also inform:

- Directors of Medical Services
- Directors of Pharmacy
- Directors of Nursing
- Drug and Therapeutics Committees and subcommittees (e.g. Medication Safety)

Expert Reference Group

Content reviewed by:

- Chief Pharmacist Unit
- Medication Safety Expert Advisory Committee
- HealthShare NSW
- State Preparedness and Response Branch

Clinical Excellence Commission

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CEC-MedicationSafety@health.nsw.gov.au

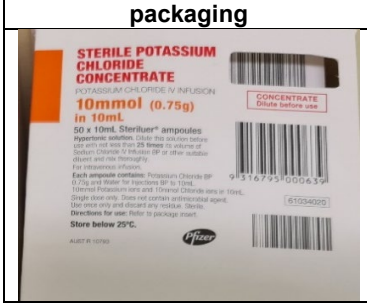
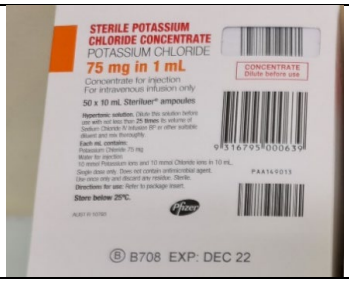
Internet Website:
http://www.health.nsw.gov.au/sabs

Intranet Website
http://internal.health.nsw.gov.au/quality/sabs/

Review date

March 2022

Pfizer has changed the labelling of the outer carton packaging of 'Sterile Potassium Chloride Concentrate **10 mmol (0.75 g) in 10 mL**' ampoules to 'Sterile Potassium Chloride Concentrate **75 mg in 1 mL**' ampoules. The new label does not specify the millimole (mmol) concentration of potassium chloride prominently which is a potential safety risk. Pfizer will be revising the artwork on the outer packaging as soon as possible to address this risk, with updated packaging anticipated from early 2022. The Therapeutic Goods Administration (TGA) is urgently investigating this issue and will be contacting Pfizer directly to discuss relevant corrective actions. TGA advice will be communicated as it becomes available.

Original outer carton packaging	New outer carton packaging	Ampoule contained within both original and new packaging
		

Background

Intravenous potassium is a high-risk medicine used for the prevention and treatment of moderate to severe potassium deficiency (hypokalaemia), when oral therapy is not possible or rapid replacement is necessary. Clinicians are most familiar with potassium concentrations and doses specified in millimoles (mmol), rather than specified *only* in weight such as grams (g) or milligrams (mg).

Pfizer has made these packaging changes to align with the new labelling requirements in Therapeutic Goods Order No. 91 (refer to the Pfizer alert for their full statement). Due to these legislative changes other products are also expected to have labelling changes to their outer packaging, but no other reports of concern have been received.

Note that the labelling on the plastic ampoules inside the new box remains unchanged and retains the original description 'Sterile Potassium Chloride Concentrate **10 mmol (0.75 g) in 10 mL**'. The product formulation and concentration also remain unchanged.

For paper-based prescribing and within Electronic Medication Management (EMM) systems, the concentration of intravenous potassium chloride products and the prescribed dose should continue to be expressed in millimoles (mmol). A local determination may also be made to include weight such as grams (g) or milligrams (mg).

Staff are reminded that as per NSW Health High-Risk Medicines Management Policy PD2020_045, '*potassium chloride ampoules should not be available as ward stock unless included in the District or Health Service Drug and Therapeutics Committee approved list of authorised clinical areas.'* Wherever possible, potassium oral formulations or pre-mixed infusion bags should be used in preference to concentrated injections.

Recommended actions by Local Health Districts/Networks

1. Distribute this Safety Notice to all stakeholders and clinical departments who may use this product.
2. Pharmacy staff should:
   a. Ensure that products supplied with the outer carton packaging label 'Sterile Potassium Chloride Concentrate **75 mg in 1 mL'** are appropriately over-labelled to prominently display the potassium chloride concentration in millimoles (mmol), prior to distribution to clinical areas. Refer to page 2 for an *example* of an appropriate over-label.
   b. Identify any clinical areas where this product may already be held and if required, ensure that the outer carton packaging is appropriately over-labelled.
   c. Ensure that dispensing labels for intravenous potassium chloride include the millimole (mmol) quantity in the product description, and where required, in the directions for use. ***Continued on page 2***

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Recommended actions by Local Health Districts/Networks

3. Clinicians should continue prescribing intravenous potassium chloride in millimoles (mmol), on both paper medication charts and in EMM systems.
4. Local ICT teams should confirm that EMM systems continue to list the product concentration and prescribed dose appropriately in millimoles (mmol). Weight units such as grams (g) or milligrams (mg) may also be included.
5. Relevant clinical staff should be educated about the labelling change on the outer carton packaging.
6. Facilities should assess if there is variation in how this product description is locally expressed and whether this could confuse staff. Standardisation is highly desirable, but if this is not possible staff education may be needed to highlight equivalent expressions which are *locally* used. Examples of equivalent potassium chloride concentration expressions include:
    - potassium chloride 75 mg in 1 mL
    - potassium chloride 10 mmol (0.75 g) in 10 mL
    - potassium chloride 10mmol (750 mg) in 10 mL
    - potassium chloride 7.5% (1 mmol/mL) 10 mL
7. Clinical incidents relating to the labelling/packaging of potassium chloride injection should be reported via the local incident management system.
8. Confirm receipt and distribution of this notice to CEC-MedicationSafety@health.nsw.gov.au **within 24 hours**.

Example of an appropriate over-label