Safety Notice 012/23

Issue date
18 May 2023

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, Managers and Staff of:
- Surgery, Anaesthetics
- Intensive Care Units
- Emergency
- NSW Ambulance
- Medical
- Nursing/Midwifery
- Pharmacy

Drug & Therapeutics Committees
All other relevant clinicians and clinical departments where these products are prescribed, stored and administered.

Expert Reference Group:
- Medicines Shortage Assessment and Management Team
- Medication Safety Expert Advisory Committee

Clinical Excellence Commission
Tel: 02 9269 5500
Email
Internet
Intranet

Review date
December 2023

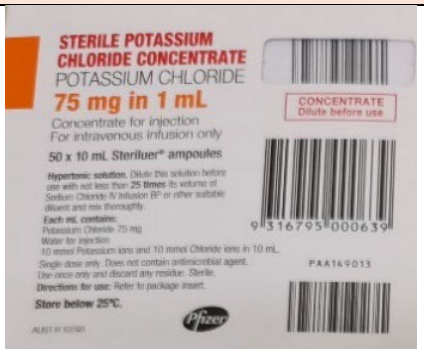
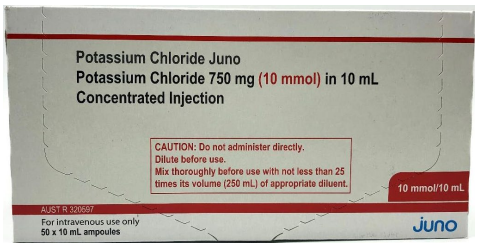
Disruption to supply: Potassium chloride (Pfizer) concentrate 10 mmol (750 mg) in 10 mL injection ampoule

Situation
There is a current disruption to supply of the Australian registered product potassium chloride (Pfizer) concentrate 10 mmol (750 mg) in 10 mL injection ampoule (AUST R: 10793) due to manufacturing issues. Supply may return from December 2023.

An alternative Australian registered product, potassium chloride (Juno) 10 mmol (750 mg) in 10 mL concentrated injection ampoule (AUST R: 320597) is currently available.

Background
- Intravenously administered potassium chloride is indicated for the prevention and treatment of hypokalaemia in patients who are unable to take potassium orally or when rapid replacement is required. Potassium chloride concentrate **must be diluted** prior to intravenous administration.
- Potassium (intravenous) is a high-risk medicine as incidents involving administration of intravenous potassium in error may cause serious harm or death
- A Potassium Standard exists as part of the NSW Health Policy Directive *High-Risk Medicines Management* PD2020_045.

Assessment
The Pfizer and Juno products are identical in active ingredient, strength, storage requirements and excipients. There are differences in appearance between the two brands (see **Table 1** below).

Product	Potassium chloride (Pfizer) 10 mmol (750 mg) in 10 mL	Potassium chloride (Juno) 10 mmol (750 mg) in 10 mL
Outer packaging		
Ampoule		

Incidents have occurred in the past involving the inadvertent administration of potassium chloride as an intravenous bolus. The similar appearance of potassium chloride ampoules to sodium chloride ampoules ('look-alike') has been a contributing factor. The Juno product does not have the specific safety features present on the Pfizer product (e.g. having 'KCl' printed on the pull off tab of the ampoule) to prevent selection errors. It is recommended that clinicians be made aware of the significant potential risk for selection errors, and employ mitigation strategies to minimise the risk.

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Clinical Recommendations

- The current availability of potassium chloride (Pfizer) concentrate 10 mmol (750 mg) in 10 mL injection ampoules in each facility should be assessed, ensuring all locations of stock are identified. Consideration should be given to replacing potassium chloride ampoules where possible with **commercially prepared pre-mixed intravenous potassium chloride solutions.** Please note – the NSW Medicines Formulary Committee recently approved potassium chloride 40 mmol in 100 mL sodium chloride 0.9% intravenous infusion bag for listing on the NSW Medicines Formulary.
- Actions to prepare for the safe transition to the potassium chloride (Juno) product are to be implemented with liaison between representatives from the local Pharmacy Department, Drug and Therapeutic Committee and relevant clinicians.

In accordance with NSW Health Policy Directive *High-Risk Medicines Management* PD2020_045 and the *Medication Handling* Policy Directive PD2022_032, clinicians are to be reminded of the following:

- Orders for intravenous potassium salts must be expressed in millimoles (mmol) not milligram per litre (mg/L) or percent (%).
- 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.
- Potassium chloride ampoules must be physically separated from other ampoules of similar appearance and retained in original packaging until immediately prior to use.
- Clinicians should adhere to local policy regarding safe and accurate medication administration, including the 5 Rights (right patient, right drug, right dose, right time and right route) and independent second person checks. These checks should include (but are not limited to) carefully reading the medication label to verify the name, strength, form and route of administration against the medication order, **rather than relying on packaging or label recognition.**
- An independent second person check is required prior to the preparation and administration of intravenous potassium chloride.

Consider the Australian Commission on Safety and Quality in Health Care (ACSQHC) *Principles for the safe selection and storage of medicines*, including (but not limited to):

- Utilising barcode scanning to conduct checks when restocking automated storage systems, and during the dispensing process in Pharmacy Departments.
- Considering the use of additional warning labels on shelving or medicine packaging to differentiate products or to alert to the potential risk of selection error involving look-alike products (e.g., 'PLEASE CHECK CAREFULLY – medicine with a similar name or appearance').

Required actions for the Local Health Districts/Networks

1. Distribute this Safety Notice to all relevant clinicians and clinical departments where intravenous potassium chloride concentrate is prescribed, stored and administered, and include this Safety Notice in relevant handovers and safety huddles.
2. Undertake a local risk assessment, and develop strategies to manage the disruption to the supply of potassium chloride (Pfizer) 10 mmol (750 mg) in 10 mL injection ampoules which incorporates the recommendations provided in this Safety Notice.
3. Ensure a system is in place to document actions taken in response to this Safety Notice.
4. Report any incidents associated with this disruption to supply and the transition to potassium chloride (Juno) into the local incident management system e.g., ims+.
5. Confirm receipt and distribution of this Safety Notice **within 72 hours** to: CEC-MedicationSafety@health.nsw.gov.au.