



Safety Notice 003/14

4 August 2014

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Director Private Health Care

Action required by:

- Chief Executives
- Directors of Clinical Governance

We recommend you also inform:

- Emergency Departments
- Intensive Care Units
- Operating Suites
- Directors of Pharmacy
- Drugs and Therapeutic Committees
- Directors of Nursing

Expert Reference Group

Content reviewed by:

- Business Procurement Services, HealthShare
- Pharmaceutical Services Unit, NSW Ministry of Health
- Office of the Chief Health Officer

Clinical Excellence Commission

Tel. 02 9269 5500
 Fax. 02 9269 5599

Email:
quality@cec.health.nsw.gov.au

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

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

POTASSIUM CHLORIDE BP 10mmol/10mL AMPOULES DISRUPTION TO SUPPLY

Background

Sterile Potassium Chloride Concentrate 10mmol (750mg)/10mL IV Plastic Steriluer 10mL ampoules AUST R 10793 (Pfizer Australia Pty Ltd) is currently unavailable due to a manufacturing malfunction. This is likely to continue until early to mid-September 2014.

There is an alternative supply of potassium chloride in a 10mmol/10mL ampoule (Astra Zeneca Pty Ltd) however there is limited supply of this product until late August 2014.

Potassium chloride in an infusion concentrate of 30mmol/10mL (Phebra Pty Limited) is available.

Sterile potassium chloride concentrate is used for the prevention and treatment of potassium deficiency (hypokalaemia) in patients unable to take potassium orally and when administration of premixed intravenous solutions of potassium chloride is not appropriate. It is also used in the treatment of digitalis intoxication.

Due to the supply situation a shortage of potassium chloride 10mmol/10mL ampoules may occur during the month of August 2014.

In the interim (until supply is reinstated) the following measures should be put into place:

Local Health Districts/Networks should

1. Distribute this notice to key stakeholders and all clinical departments.
2. Assess the current status of potassium chloride ampoules availability in each facility, ensuring all locations of stock are identified including disaster stores.
3. Develop a local plan to manage the supply shortage, making every effort to reserve available supplies of the 10mmol/10mL ampoules for critical situations where use of premixed potassium chloride intravenous solutions is not appropriate.
4. Inform clinical department heads of the need to review protocols specific to their clinical practice and produce advice on safe ways of storing and using the higher concentration of 30mmol/10mL if stocks are required during the shortage.
5. Make clinicians aware of the limited availability during the month of August 2014 of the 10mmol/10mL preparation and to be aware of protocols relating to the use of higher concentrations.
6. Once supplies of the 10mmol/10mL preparation are available any higher concentrations introduced during the shortage must be returned to pharmacy and clearly segregated from other strengths.

Further information

Alternative supply options of Special Access Scheme (SAS) products in the 10mmol/10mL presentation are being investigated, details of which can be obtained by emailing contract902@hss.health.nsw.gov.au

The policy directive PD2012_003 High-Risk Medicines Management provides further information regarding the safe intravenous use of potassium.

Suggested actions by Local Health Districts/Networks

1. Forward information to appropriate area for action.
2. Ensure a system is in place to document actions taken.