Safety Notice 026/21

Safety risks due to new labelling of intravenous calcium gluconate

15 December 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:

- Medication Safety Expert Advisory Committee

Clinical Excellence Commission

Tel. 02 9269 5500

Email: CEC-MedicationSafety@health.nsw.gov.au

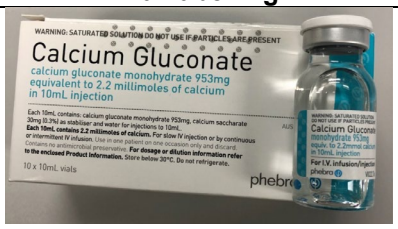
Internet Website: http://www.health.nsw.gov.au/sabs

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

Review date

June 2022

Phebra has changed the labelling of '**Calcium Gluconate Injection 2.2 mmol of calcium in 10 mL**' to '**Calcium Gluconate Injection - calcium gluconate monohydrate 931 mg in 10 mL solution for injection**'. The outer carton packaging and vials specify the millimole (mmol) concentration of calcium in the smaller text, however it is not prominent which is a potential safety risk.

Original outer carton packaging and vial labelling	New outer carton packaging and vial labelling
	

Background

Intravenous calcium gluconate is used for the treatment of magnesium toxicity, severe hydrofluoric acid burns, severe hypocalcaemia in patients who cannot receive oral supplementation, severe hyperkalaemia not due to digoxin toxicity and acute calcium channel blocker poisoning with heart block. Clinicians are most familiar with calcium concentrations and doses specified in millimoles (mmol), rather than specified *only* in weight such as grams (g) or milligrams (mg).

Phebra has made these packaging changes to align with the new labelling requirements in Therapeutic Goods Order No. 91 (refer to the Phebra letter for their full statement). Due to these legislative changes, other products are also expected to have labelling changes to their packaging.

There has also been a change to the formulation of calcium gluconate injection – the amounts of calcium gluconate (now 931 mg, previously 953 mg) and calcium saccharate (now 46 mg, previously 30 mg) have been modified to improve stability. The calcium ion concentration however **remains equivalent** to the previous formulation, i.e. 2.2 millimoles of calcium ions in 10 mL, and thus changes to dosing are not required.

For paper-based prescribing and within Electronic Medication Management (EMM) systems, the concentration of intravenous calcium gluconate products and the prescribed dose should continue to be expressed in millimoles (mmol). Weight units such as grams (g) or milligrams (mg) may also be included.

It should be noted that older local policies or guidelines may refer to calcium gluconate injection as "calcium gluconate 10%" (it was formerly known by this name). Any documents or EMM order sentences using this description should be updated accordingly.

Recommended actions by Local Health Districts/Networks

1. Distribute this Safety Notice to all stakeholders and clinical departments who may use this product.
2. Relevant clinical staff should be educated about the labelling change on the outer carton packaging and vials. It should be highlighted that the millimole (mmol) concentration of calcium still appears on both labels, however in smaller text.
3. Pharmacy staff should:
   a. Consider during a period of transition to over-label vials and outer packaging to prominently display the calcium concentration in millimoles (mmol), prior to distribution to clinical areas. This may involve attaching labels to individual vials in a way that does not obstruct key information including the product batch and expiry date. 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 and vials is appropriately over-labelled and consider the use of 'shelf-talkers'.
   c. Ensure that dispensing labels for intravenous calcium gluconate include the millimole (mmol) quantity in the product description and where required in the directions for use. **PTO**

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Safety risks due to new labelling on the outer carton packaging of intravenous calcium gluconate vials

Recommended actions by Local Health Districts/Networks

4. Clinicians should continue prescribing intravenous calcium gluconate in millimoles (mmol), on both paper medication charts and in EMM systems.
5. 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. Order sentences using the former "calcium gluconate 10%" description will need to be updated.
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.
7. Clinical incidents relating to the labelling/packaging of calcium gluconate 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 48 hours**.

Example of an appropriate over-label –

Calcium gluconate solution for injection
931 mg in 10 mL
Equivalent to 2.2 mmol calcium ions in 10 mL