

21st March 2022

Dear Valued Customer,

Re: Phebra Electrolyte Product Labelling Update

Phebra supplies a number of electrolyte products, each with a carton and vial label approved by the TGA and in alignment with the requirements of the current TGA labelling Order TGO-91¹ Medicine Label Guidance. On the current labelling, the millimole (mmol) strength is stated within the content on the main panel.

The TGA has recommended that each carton and vial label be amended to give the millimole (mmol) concentration more prominence. The amended packaging will have the millimole (mmol) strength displayed more prominently adjacent to the name of the medicine and the active ingredient/s.

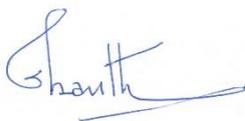
Please note that the mmol concentrations of the electrolyte products have not and will not be changed. The labelling amendment relates to achieving greater prominence of the mmol concentration statement on the label.

To ensure uninterrupted supply while Phebra update the packaging in line with this recommendation, the products listed on the following page will continue to be supplied in their current labelling. A notification will be forwarded for each electrolyte product when the new packaging is introduced.

Phebra requests that this notification is forwarded to relevant departments and healthcare professionals within your hospital who may use these electrolyte products.

For further information, please contact Phebra's Medical Affairs Department at medical@phebra.com or on 02 9420 9199.

Yours faithfully,



Shanthi Vijayakumar
Regulatory Affairs Manager

To 'opt out' of receiving product information communications from Phebra, other than safety-related information, reply to this email with 'opt out' in the subject line.

¹ <https://www.tga.gov.au/medicine-labels-guidance-tgo-91-and-tgo-92>

PHEBRA ELECTROLYTE PRODUCTS

Phebra product code	Product Name	AUST R	Millimole Concentration
INJ017	Calcium Chloride (10%) Injection, 1 g/10 mL	137325	Each 10 mL vial contains 6.8 mmol of calcium ions and 13.6 mmol of chloride ions.
INJ011	Magnesium Sulfate Heptahydrate (50%) Concentrated Injection, 5 g/10 mL	160885	Each 10 mL vial contains 20 mmol of magnesium ions.
INJ056	Magnesium Sulfate Heptahydrate (50%) Concentrated Injection, 2.5 g/5 mL	23076	Each 5 mL vial contains 10 mmol of magnesium ions.
INJ014	Potassium Chloride (22.3%) Concentrated Injection, 2.23 g/10 mL	23073	Each 10 mL vial contains 30 mmol of potassium ions and 30 mmol of chloride ions.
INJ089	Potassium Dihydrogen Phosphate (13.6%) Concentrated Injection, 1.361 g in 10 mL	23183	Each 10 mL vial contains 10 mmol of potassium ions, 10 mmol of phosphate ions and 20 mmol of hydrogen ions.
INJ099	Sodium Bicarbonate (8.4%) Injection, 840 mg/10 mL	131067	Each 10 mL vial contains 10 mmol of sodium ions and 10 mmol of bicarbonate ions.
INJ127	Sodium Bicarbonate (8.4%) Injection, 8.4 g/100 mL	48376	Each 100 mL vial contains 100 mmol of sodium ions and 100 mmol of bicarbonate ions.
INJ072	Sodium Chloride (0.9%) Injection, 900 mg/100 mL	48349	Each 100 mL vial contains 15.4 mmol of sodium ions and 15.4 mmol of chloride ions.
INJ027	Sodium Chloride (23.4%) Concentrated Injection, 2.34 g/10 mL	23119	Each 10 mL vial contains 40 mmol of sodium ions and 40 mmol of chloride ions.
INJ082	Sodium Dihydrogen Phosphate (15.6%) Injection, 1.56 g/10 mL	Schedule 5A*	Each 10 mL vial contains 10 mmol of sodium ions and 10 mmol of phosphate ions.
INJ062	Zinc Chloride (0.53%) Concentrated Injection, 10.6 mg/2 mL	22876	Each 2 mL vial contains 0.078 mmol of zinc ions and 0.156 mmol of chloride ions.

*Supplied in Australia as exempt goods as per Section 18(1) of the Therapeutic Goods Act, Schedule 5A, sub-regulation 12 (1A) of the Therapeutic Goods Regulations, as a supply contract to hospitals and public institutions.