NEW ZEALAND DATA SHEET

1. PRODUCT NAME

Glycophos® 306.1 mg/mL Infusion, concentrate

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 mL solution contains:
Sodium glycerophosphate pentahydrate 306.1 mg (corresponds to sodium glycerophosphate anhydrous 216 mg).

Glycophos® contains 1 mmol of glycerophosphate and 2 mmol of sodium per mL.

Osmolality: 2800mOsm/kg water.
pH: 7.4

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Glycophos® is a sterile clear, colourless solution.
Infusion, concentrate.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Glycophos® is indicated in adult patients, children, infants and neonates as a supplement in intravenous nutrition to meet the requirement of phosphate.

4.2 Dose and method of administration

Dose
Adults:
The recommended dosage is individual. The recommended daily dosage of phosphate during intravenous nutrition would normally be 10-20 mmol. This can be met by using 10-20 mL of Glycophos® added to the infusion solution or to the admixture for which compatibility has been proved.

Children, Infants and Neonates:
The recommended dosage is individual. The recommended dose for children, infants and neonates is 1.0-1.5 mmol/kg body weight/day.

Method of administration
Intravenous Infusion.
Glycophos® must not be given undiluted. The infusion must be administered over a period of at least 8 hours.

4.3 Contraindications

Glycophos® should not be given to patients in a state of dehydration or with hypernatraemia, hyperphosphataemia, severe renal insufficiency or shock.

4.4 Special warnings and precautions for use
Glycophos® should be used with caution in patients with impaired renal function. The phosphate status of all patients should be monitored regularly.

Glycophos® must not be given undiluted.

4.5 Interaction with other medicines and other forms of interaction
No interactions with other drugs have been observed, but a moderate fall in serum phosphate can be seen during carbohydrate infusions.

4.6 Fertility, pregnancy and lactation
Pregnancy
Animal reproduction studies or clinical investigations during pregnancy have not been carried out with Glycophos®. However, the requirements of phosphate in a pregnant woman are slightly increased compared to non-pregnant women.

No adverse risks to the foetus are expected when Glycophos® is administered at the recommended dosage.

Breast-feeding
No adverse effects are expected for a nursing child.

Fertility
There is no fertility data available.

4.7 Effects on ability to drive and use machines
No effects on the ability to drive and use machines are to be expected.

4.8 Undesirable effects
Glycophos® is generally safe and very well-tolerated in recommended doses.

In two (2), two-way cross-over clinical trials, the observed drug-related Treatment-Emergent Adverse Events (TEAEs) with investigator implied causality in both Glycophos® and comparator pooled groups are presented in the table below.

Drug-related TEAEs, n (%) of patients	Glycophos® (n=35)	Comparator (n=35)
Metabolism and nutrition disorders Hypocalcaemia	4 (11%)	5 (14%)
Nervous system disorders Headache	1 (3%)	-

No other adverse effects are expected with glycerophosphate.

4.9 Overdose
No adverse effects of an overdose have been reported. Most patients in need of intravenous nutrition have an increased capacity to handle glycerophosphate. See section 4.3 Contraindications.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Electrolyte solution, ATC code: B05XA14
Glycophos® is a concentrated additive solution of phosphate and sodium.

5.2 Pharmacokinetic properties
To become available, it is necessary for the phosphate group to be hydrolysed from the glycerophosphate molecule. The hydrolysis occurs maximally at a plasma concentration of >0.7 mmol/L. Assuming that all hydrolysis of glycerophosphate takes place in plasma, about 12-15 mmol of sodium glycerophosphate will be hydrolysed each day in individuals with normal serum alkaline phosphatase.

No pharmacokinetic data is available for neonates. However, hyperphosphatemia is unlikely at the recommended dosage.

Intravenously administered phosphate is not taken up by the tissue and it is excreted almost entirely in the urine.

5.3 Preclinical safety data
None available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Hydrochloric acid, water for injection solution.

6.2 Incompatibilities
Glycophos® may only be mixed with other medicinal products for which compatibility has been documented. See section 6.6 “Special precautions for use, disposal and other handling”.

6.3 Shelf life
Shelf Life before mixing
3 years

Shelf Life after mixing
Chemical and physical in-use stability of the mixed product has been demonstrated for 24 hours at 20-25°C.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would not normally be longer than 24 hours at 2 to 8ºC.

6.4 Special precautions for storage
Store below 25°C, do not freeze.
Do not use after the expiry date stated on the label.
Any remaining solution from the opened container must be discarded.

6.5 Nature and contents of container
Polypropylene vial.
Pack size: 10 x 20 mL

Polypropylene ampoule.
Pack size: 20 x 20 mL

6.6 Special precautions for use, disposal and other handling
Glycophos® must not be given undiluted.

Additions should be made aseptically.

Compatibility
Glycophos® is used as an additive to TPN admixtures in compounded bags where compatibility data are available. Compatibility of Glycophos® has been demonstrated for use with the named branded products SMOFlipid, Aminoven 10%, Addaven, Soluvit N and Vitalipid N in defined amounts and standard IV solutions of glucose and electrolytes in defined concentrations. Glycophos® can also be added to the SmofKabiven and Kabiven range of products.

In addition,

- up to 10 mmol glycerophosphate and 10 mmol calcium (as $CaCl_2$) can be added to 1000 mL glucose 50 mg/mL,
- up to 20 mmol glycerophosphate and 20 mmol calcium can be added to 1000 mL Glucose 200 mg/mL and
- up to 60 mmol glycerophosphate and 24 mmol calcium can be added to 1000 mL Glucose 500 mg/mL.

Infusion time
The infusion solution must be administered over a period of at least 8 hours.

Stability
When additions are made to an infusion solution, the diluted product should be stored at 2 to 8°C. The infusion should be completed within 24 hours from the time of preparation to avoid microbiological contamination. Any excess solution in an opened package must be discarded, and must not be kept for later use.

7. MEDICINE SCHEDULE
General Sale Medicine

8. SPONSOR
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9. DATE OF FIRST APPROVAL
22 February 2007

10. DATE OF REVISION OF THE TEXT

07 January 2019