

DATA SHEET

NAME OF MEDICINE

GLYCOPHOS (Sodium glycerophosphate pentahydrate 306.1 mg/mL corresponds to sodium glycerophosphate anhydrous 216 mg/mL)
Concentrate for Solution for Infusion

PRESENTATION

GLYCOPHOS is a sterile clear, colourless concentrate containing glycerophosphate and sodium for addition to infusion solutions.

USES

Actions

Glycerophosphate is a metabolic intermediate in fat metabolism and any pharmacodynamic effects other than maintaining the normal metabolic pathways are unlikely.

Pharmacokinetics

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.

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

INDICATIONS

GLYCOPHOS is indicated in adult patients and infants as a supplement in intravenous nutrition to meet the requirement of phosphate.

DOSAGE AND ADMINISTRATION

GLYCOPHOS must not be given undiluted.

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.

Infants:

The recommended dosage is individual. The recommended dose for infants and neonates is 1.0-1.5 mmol/kg body weight/day.

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

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.

Use in pregnancy and lactation

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 events are to be expected when GLYCOPHOS is administered during pregnancy.

Effects on ability to drive and use machines

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

ADVERSE REACTIONS

No adverse effects related to glycerophosphate have been reported.

INTERACTIONS

No interactions with other drugs have been observed, but a moderate fall in serum phosphate can be seen during carbohydrate infusions.

OVERDOSAGE

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

PHARMACEUTICAL PRECAUTIONS

Instructions for use

GLYCOPHOS must not be given undiluted.

GLYCOPHOS may only be added to or mixed with other medicinal products for which compatibility has been documented.

Additions should be made aseptically.

Up to 120 mL of GLYCOPHOS and 48 mmol of calcium (as calcium chloride) can be added to 1000 mL Vamin Glucose, Vamin 14, Vamin 14 Electrolyte Free, Vamin 18 Electrolyte Free and Vaminolact.

Up to 10 mL of GLYCOPHOS and 10 mmol of calcium (as calcium chloride) can be added to 1000 mL Glucose 50 mg/mL.

Up to 20 mL of GLYCOPHOS and 20 mmol of calcium (as calcium chloride) can be added to 1000 mL Glucose 200 mg/mL.

Up to 60 mmol of GLYCOPHOS and 24 mmol of calcium (as calcium chloride) can be added to 1000 mL Glucose 500 mg/mL.

The infusion time should not be less than 8 hours.

When additions are made to an infusion solution, the infusion should be completed within 24 hours from preparation to prevent microbiological contamination. The left over contents of open vials should be discarded and not kept for later use.

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.

MEDICINES CLASSIFICATION

General Sale Medicine

PACKAGE QUANTITIES

20 mL plastic vials for injection packed in boxes of 10

FURTHER INFORMATION

The active substance is sodium glycerophosphate pentahydrate 306.1 mg/ml corresponding to 216 mg/ml sodium glycerophosphate anhydrous. Other ingredients are hydrochloric acid added to pH 7.4 and water for injections to 1 mL.

The active ingredient in 1 mL of GLYCOPHOS corresponds to 1 mmol of phosphate and 2 mmol of sodium.

Osmolality: 2760 mosm/kg water.

NAME AND ADDRESS

Sponsor

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31st March, 2010