01-58-07-047A

FRESENIUS KABI

626

Glycophos™

Concentrate for solution for infusion

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DESCRIPTION

Glycophos is a sterile concentrate for solution containing sodium glycerophosphate for addition to infusion solutions.

COMPOSITION

The active substance is sodium glycerophosphate pentahydrate 306,1 mg, corresponding to 216 mg sodium glycerophosphate anhydrous.
The other ingredients are hydrochloric acid added to pH 7.4 and water for injections to 1 ml.
Osmolality: 2760 mosm/kg water.
The active ingredients in 1 ml of Glycophos corresponds to 1 mmol of phosphate and 2 mmol of sodium.

INDICATIONS

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

CONTRAINDICATIONS

- state of dehydration,
- hypernatraemia,
- hyperphosphataemia,
- severe renal insufficiency,
- shock.

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.

INTERACTIONS

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

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.

DOSAGE AND ADMINISTRATION

Glycophos must not be given undiluted.

Adults:

The recomended 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.

ADVERSE EFFECTS

No adverse effects related to glycerophosphate have been reported.

INSTRUCTIONS FOR USE

The addition of Glycophos should be performed aseptically.
Glycophos may only be added to or mixed with other medicinal products for which compatibility has been documented.
Up to 120 ml Glycophos and 48 mmol of calcium (as Calcium chloride) can be added to 1000 ml Vamin Glucose, Vamin 9 Electrolyte Free, 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 of Glucose 200 mg/ml.
Up to 60 ml of Glycophos and 24 mmol of calcium (as Calcium chloride) can be added to 1000 ml Glucose 500 mg/ml.
With regards to the risk of contamination the mixture should be used within 24 hours.

OVERDOSE

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

STORAGE

Do not store above 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.

PACK SIZE

20 ml plastic ampoules packed in boxes of 20.
20 ml plastic vials packed in boxes of 10.

DATE OF REVISION

April 2018.

Manufactured by:

HP Halden Pharma AS, Halden, Norway for
Fresenius Kabi AB, Uppsala, Sweden

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