SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sodium Glycerophosphate 21.6% concentrate for solution for infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient	Quantity/ml	Quantity/20 ml vial
Sodium glycerophosphate Pentahydrate	306.1 mg*	4320 mg

* Corresponds to 216 mg sodium glycerophosphate

The active ingredient in 1 ml of Sodium Glycerophosphate 21.6% concentrate for solution for infusion corresponds to

Phosphate	1 mmol	20 mmol
Sodium	2 mmol	40 mmol

For the list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Concentrate for solution for infusion

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Sodium Glycerophosphate 21.6% concentrate for solution for infusion is indicated in adult patients as a supplement in intravenous nutrition to meet the requirements of phosphate.

4.2 Posology and method of administration

Posology

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 Sodium Glycerophosphate 21.6% concentrate for solution for infusion added to the infusion solution or to the admixture for which compatibility has been proved.

Method of administration

Sodium Glycerophosphate 21.6% concentrate for solution for infusion must not be given undiluted.

For instructions on dilution of the medicinal product before administration, see section 6.6.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Sodium Glycerophosphate 21.6% concentrate for solution for infusion should not be given to patients in a state of dehydration or with hypernatraemia, hyperphosphataemia, severe renal insufficiency or shock.

4.4 Special warning and precautions for use

Sodium Glycerophosphate 21.6% concentrate for solution for infusion should be used with caution in patients with impaired renal function. The phosphate status of all patients should be monitored regularly.
Sodium Glycerophosphate 21.6% concentrate for solution for infusion must not be given undiluted.

4.5 Interaction with other medicinal products 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 Sodium Glycerophosphate 21.6% concentrate for solution for infusion. 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 Sodium Glycerophosphate 21.6% concentrate for solution for infusion is administered during pregnancy.

4.7 Effects on ability to drive and use machines

Sodium Glycerophosphate 21.6% concentrate for solution for infusion has no influence on the ability to drive and use machines.

4.8 Undesirable effects

No adverse effects related to sodium glycerophosphate have been reported.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

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 also 4.3 "Contraindications".

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic group, ATC code: B05X A14 Sodium Glycerophosphate

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

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.

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

5.3 Preclinical safety data

Preclinical safety studies on Sodium Glycerophosphate 21.6% concentrate for solution for infusion demonstrated good tolerance.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Hydrochloric acid

Water for Injections

6.2 Incompatibilities

Sodium Glycerophosphate 21.6% concentrate for solution for infusion may only be added to or mixed with other medicinal products for which compatibility has been documented. See section 6.6.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not store above 25°C. Do not freeze. From a microbiological point of view, the product should be used immediately.

6.5 Nature and contents of container

Vial for injection, polypropylene plastic
Pack size: 10 x 20 ml

Ampoules for injection, polypropylene plastic
Pack size: 20 x 20 ml

6.6 Special precautions for disposal and other handling

Sodium Glycerophosphate 21.6% concentrate for solution for infusion must not be given undiluted.

Compatibility

Additions should be made aseptically.

Up to 120 ml of Sodium Glycerophosphate 21.6% concentrate for solution for infusion and 48 mmol of calcium (as CaCl2 or Ca gluconate) can be added to 1000 ml Vamin 14, Vamin 14 Electrolyte Free, Vamin 18 Electrolyte Free and Vaminolact.

Up to 10 ml of Sodium Glycerophosphate 21.6% concentrate for solution for infusion and 10 mmol of calcium (as CaCl2 or Ca gluconate) can be added to 1000 ml Glucose 50 mg/ml.

Up to 20 ml of Sodium Glycerophosphate 21.6% concentrate for solution for infusion and 20 mmol of calcium (as CaCl2 or Ca gluconate) can be added to 1000 ml Glucose 200 mg/ml.

Up to 60 mmol of Sodium Glycerophosphate 21.6% concentrate for solution for infusion and 24 mmol of calcium (as CaCl2 or Ca gluconate) can be added to 1000 ml Glucose 500 mg/ml.

Infusion time

The infusion time should not be less than 8 hours.

Stability

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 opened bottles/vials/ampoules should be discarded and not kept for later use.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 08828/0147

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28 July 2003

Date of latest renewal: 09 February 2009

10 DATE OF REVISION OF THE TEXT

20/12/2018