SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Addiphos concentrate for solution for infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of Addiphos contains:

Potassium Dihydrogen Phosphate 170.1 mg	Ph. Eur.
Disodium Phosphate Dihydrate 133.5 mg	Ph. Eur.
Potassium Hydroxide Ph. Eur.	14.0 mg

One vial (20 ml Addiphos) provides the following:

Phosphate	40 mmol
Potassium	30 mmol
Sodium	30 mmol

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Concentrate for solution for infusion.
A clear, colourless aqueous sterile solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

To provide a source of phosphate during parental nutrition, by its addition to infusion fluids e.g. Vamin solutions and glucose solutions. It also provides potassium and sodium.

4.2 Posology and method of administration

Posology

Adults

A daily requirement for phosphate during complete intravenous nutrition would normally be within the range 10-40 mmol. This can be met by using 5-20 ml of Addiphos.

5-20 ml Addiphos also provides 7.5-30 mmol each of potassium and sodium. The infusion should be given intravenously at a rate corresponding to not more than 10 mmol K_+ per hour so as to avoid hyperkalaemia and also within the maximum infusion rate for Vamin.

Paediatric population
Dosage should be reduced appropriately according to age and weight.

Method of administration

Intravenous infusion after dilution.

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

4.3 Contraindications

This preparation should not be administered undiluted.

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

Addiphos should not be used in patients with hyperkalaemia such as is associated with adrenal or severe renal insufficiency. It should not be given in the presence of dehydration without fluid replacement.

A cloudy solution or one containing a precipitate must not be used.

4.3 Special warnings and precautions for use

Care should be exercised in patients with cardiac disease, diabetes mellitus, renal dysfunction or hepatic insufficiency.

Infusion of potassium may depress cardiac function and counteract the effects of digitalis.

Simultaneous infusion of potassium and glucose will achieve a lower serum potassium level than when potassium is given alone.

Plasma levels and clinical signs suggesting hyperkalaemia require discontinuation.

The addition of Addiphos should be performed aseptically immediately before the start of the infusion and should be used within 24 hours.

Each vial of Addiphos is for single use only. It should be mixed well immediately after addition to the infusion solution.

4.5 Interactions with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Addiphos is a solution for use as a supplement in parenteral nutrition regimens, providing phosphate, potassium and sodium. No hazard is expected if used in pregnancy at the recommended dose.

No animal studies have been performed. However, successful outcomes with administration during pregnancy have been recorded.

4.7 Effects on ability to drive and use machines

Not relevant.

4.4 Undesirable effects

There have been no reported undesirable effects observed during the administration of Addiphos.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation 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

4.5 Overdose

Addiphos in over dosage may lead to hyperkalaemia, depressing cardiac function. Insulin may be required to reverse this effect, administered intravenously concomitant with glucose.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: electrolytes in combination with other drugs
ATC Code: B05XA31

Addiphos is formulated to supply phosphate; potassium and sodium in a concentrate form suitable for addition to parenteral nutrition regimens.

5.2 Pharmacokinetic properties

Addiphos is an electrolyte supplement without interest for pharmacokinetic studies.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections Ph Eur

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products, except those mentioned in section 6.6

6.3 Shelf life

3 years.

6.2 Special precautions for storage

Do not store above 25°C.
Keep vial in outer carton.

6.5 Nature and contents of container

Plastic vials of polypropylene
Pack size: 10 x 20ml

6.2 Special precautions for disposal and other handling

For single use only.
Ensure the preparation is well mixed immediately after addition to the infusion solution.
Any unused solution should be discarded.

This preparation must not be administrated undiluted.

A cloudy solution or one containing a precipitate must not be used.

In regimens including Intralipid, it should be noted that 500 ml Intralipid 10%, 20% or 30% provides approximately 7.5 mmol organic phosphate.

Compatibility

Addiphos must only be added to solutions where compatibility is known. Contact Fresenius Kabi Ltd for full information on complete and balanced regimens.

The addition of Addiphos should be performed aseptically immediately before the start of the infusion and should be used within 24 hours unless the mixture is refrigerated when it may be used within 48 hours of preparation.

Compatibility has been demonstrated with the following solutions up to the maximum levels indicated.

Infusion Solution (500 ml volume)	Maximum volume of Addiphos which may be Added to 500 ml of infusion solution
Vamin 9	30ml
Vamin 9 Glucose	30ml
Vamin 14	20ml
Vamin 14 Electrolyte-Free	30ml
Vamin 18 Electrolyte-Free	30ml
Glucose 5-60%	30ml

Addiphos must not be added to recommended infusants in the presence of Addamel/Additrace because of precipitation risk.

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

7 MARKETING AUTHORISATION HOLDER

Fresenius Kabi Limited
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8 MARKETING AUTHORISATION NUMBER

PL 08828/0101

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

Date of first authorisation: 31 May 1999
Date of latest renewal: 19 February 2009

10 DATE OF REVISION OF THE TEXT

25/05/2016