# 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 |
| Disodium Phosphate Dihydrate | 133.5 mg |
| Potassium Hydroxide | 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

As a phosphate, potassium and sodium supplement during complete intravenous nutrition.

### 4.2 Posology and method of administration

Posology

*Adults*
The total daily dosage is dependent upon the age, weight, clinical state and degree of deficiency of the patient and must be determined on an individual basis.

The usual daily dose is 5-20 ml of Addiphos.

*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

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

Use in patients with hyperkalaemia such as is associated with adrenal insufficiency or severe renal insufficiency.

Use in the presence of dehydration without fluid replacement.

Use of a solution which is cloudy, contains sediment, or is in any way unusual.

**4.4 Special warnings and precautions for use**

This preparation must not be administered undiluted.

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

Plasma levels and clinical signs suggesting hyperkalaemia require discontinuation of this product.

Potassium replacement therapy should be used with extreme caution in patients with cardiac disease, renal dysfunction, hepatic insufficiency or diabetes mellitus.

Simultaneous infusion of potassium and dextrose will lower the serum potassium levels attained.

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

**4.5 Interaction with other medicinal products and other forms of interactions**

None known.

**4.6 Fertility, pregnancy and lactation**

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.

**4.8 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:
HPRA Pharmacovigilance,
Earlsfort Terrace,
IRL - Dublin 2;
Tel: +353 1 6764971;
Fax: +353 1 6762517.
Website: www.hpra.ie;
E-mail: medsafety@hpra.ie.

**4.9 Overdose**

Addiphos in overdosage 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

**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.

**6.4 Special precautions for storage**

Do not store above 25°C.

**6.5 Nature and contents of container**

Polypropylene vials, containing 20 ml of a clear, colourless, aqueous, sterile solution in boxes of 10 vials.

**6.6 Special precautions for disposal and other handling**

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

<u>This preparation must not be administered undiluted.</u>

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.
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 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 Deutschland GmbH
Else-Kroener Strasse 1
Bad Homburg v.d.H 61352
Germany

**8 MARKETING AUTHORISATION NUMBER**

PA2059/024/001

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 1st April 1983
Date of last renewal: 1st April 2008

**10 DATE OF REVISION OF THE TEXT**