

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. NAME OF THE MEDICINAL PRODUCT

Addiphos<sup>®</sup>

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

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

One vial (20 ml Addiphos) provides the following:

Phosphate 40 mmol  
Potassium 30 mmol  
Sodium 30 mmol

### 3. PHARMACEUTICAL FORM

Sterile solution for addition to infusion fluids.

### 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

Intravenous infusion after dilution.

##### 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<sup>+</sup> per hour so as to avoid hyperkalaemia and also within the maximum infusion rate for Vamin.

##### Children

Dosage should be reduced appropriately according to age and weight.

#### 4.3 Contraindications

This preparation should not be administered undiluted.

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.

#### 4.4 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 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 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 applicable.

#### 4.8 Undesirable effects

None reported.

#### 4.9 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

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

See section 6.6 for compatibility information.

#### 6.3 Shelf life

3 years.

#### 6.4 Special precautions for storage

Store at 5-25°C.

#### 6.5 Nature and contents of container

Plastic vials of polypropylene.  
Pack size : 10 x 20 ml

#### 6.6 Instruction for use and handling

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

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.

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

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

### **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**

31 May 1999 / February 2009

### **10. DATE OF (PARTIAL) REVISION OF THE TEXT**

February 2009