

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Addiphos® Concentrate for Solution for Infusion

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Addiphos is and what it is used for
2. What you need to know before you use Addiphos
3. How to use Addiphos
4. Possible side effects
5. How to store Addiphos
6. Contents of the pack and other information

1. WHAT ADDIPHOS IS AND WHAT IT IS USED FOR

Addiphos provides salts into your blood stream when you cannot eat normally. Salts are chemicals required in small amounts for the body to work normally.

Addiphos is usually used as part of a balanced intravenous diet, together with proteins, fats, carbohydrates, other salts and vitamins.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ADDIPHOS

Do not use Addiphos:

- if you are allergic to the active substance(s) or any other of the ingredients of this medicine (listed in section 6). **If you develop a rash or other allergic reactions (like itching, swollen lips or face or shortness of breath), please inform your doctor, pharmacist or nurse.**
- have high potassium levels (hyperkalaemia)
- have severely impaired kidneys
- have problems with adrenal glands
- are dehydrated (not enough water in your body)

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Addiphos if you suffer from:

- impaired liver and/or kidney function
- diabetes
- heart problems

Your doctor may want to do regular blood tests to check your condition.

Addiphos **must be diluted before use**. It will be added to another solution before it is given to you. Your doctor, pharmacist or nurse will make sure it is prepared correctly before you receive Addiphos.

Addiphos should not be used if it has got particles in it. The doctor, pharmacist or nurse will check that the solution is particle free before it is administered to you.

Other medicines and Addiphos

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Inform your doctor or pharmacist if you are taking heart drugs such as digoxin or digitoxin.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Driving and using machines

Addiphos has no effect on the ability to drive and use machines.

3. HOW TO USE ADDIPHOS

You will receive your medicine by infusion (IV drip).

Your doctor or pharmacist will decide on the correct dose for you to receive.

Dosage

The recommended dose of Addiphos for adults is 5 millilitres up to 20 millilitres each day.

Children and Adolescents

Addiphos may be used in children and adolescents, and your doctor or pharmacist will reduce the dose for your child, according to their age and weight.

If you use more Addiphos than you should

It is very unlikely that you will receive more Addiphos than you should as your doctor, pharmacist or nurse will monitor you during the treatment. **An overdose of Addiphos may lead to hyperkalaemia (high potassium levels), symptoms may include:**

- **Nausea**
- **Fatigue**
- **Muscle weakness**
- **Tingling sensations**

If you think that you have received too much Addiphos, inform your doctor, pharmacist or nurse immediately.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS

Although no known undesirable effects have been reported with the use of Addiphos, like all medicines, this medicine may cause side effects.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly;

For UK - The Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

For Ireland – Via;

HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ADDIPHOS

Keep this medicine out of the sight and reach of children.

Your doctor, pharmacist and nurse are responsible for the correct storage, use and disposal of Addiphos.

Do not use this medicine after the expiry date stated on the carton and vial label. The expiry date refers to the last day of that month.

Do not store above 25 °C.

Keep vial in outer carton.

Do not use this medicine if it is cloudy or contains particles.

Any unused solution should be discarded. Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines that you no longer used. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Addiphos infusions contains

1 millilitre of Addiphos contains the following active ingredients:

Potassium Dihydrogen Phosphate 170.1 mg

Disodium Phosphate Dihydrate 133.5 mg

Potassium Hydroxide 14 mg

One vial (20 ml Addiphos) provides the following:

Phosphate 40 mmol

Potassium 30 mmol

Sodium 30 mmol

Addiphos also contains water for injections.

What Addiphos looks like and contents of the pack

Addiphos is a clear, almost colourless solution of salts. It is available in plastic ampoules that contain 20 ml of the concentrate for solution for infusion.

Marketing Authorisation Holder

MAH for UK

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