PACKAGE LEAFLET: INFORMATION FOR THE USER

B. Braun Medical Limited, Dublin 12

Potassium Phosphate 1 mmol/ml + 0.6 mmol/ml Concentrate for solution for infusion

Dipotassium Phosphate, Potassium Dihydrogen Phosphate

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 or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them,even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

In this leaflet:

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

1. WHAT POTASSIUM PHOSPHATE IS AND WHAT IT IS USED FOR

Potassium Phosphate is a concentrated solution of potassium phosphate intended for the intravenous supply of phosphate (intravenous = administration by a vein drip)..

Potassium Phosphate is used if you are lacking both potassium and phosphate at the same time.

Potassium Phosphate is administered to you by a doctor or other health professional.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE POTASSIUM PHOSPHATE

Potassium Phosphate should not be given to you if you have
- excessively high blood levels of phosphate or potassium
- abnormally low blood calcium level
- kidney impairment
- a disease or condition associated with an abnormally high blood potassium level, such as
  - lack of fluid
  - high levels of acidic substances in your blood due to decompensated diabetes (diabetic ketoacidosis)
  - kidney impairment with low urine excretion
  -a specific disease of the adrenal gland (ADDISON'S disease),

- a certain inherited disease of potassium metabolism associated with periodic paralyses (so-called *Gamstorp episodic adynamia*)
- certain metabolic disturbances that may be seen after cancer treatment (so-called tumour lysis syndrome)
- a special disorder of red blood cell formation (sickle cell anaemia)
- concurrent treatment with certain medicines promoting urine flow (see section "Taking or using other medicines")

Warnings and precautions
Special care should be taken with Potassium Phosphate if you suffer from severe heart weakness with symptoms like shortness of breath, impairment of consciousness etc.

If your kidney function worsens during treatment, administration of Potassium Phosphate will be stopped.

Rapid administration of this medicine may influence your heart action. Therefore your doctor may decide to monitor your heart function by ECG .

Your blood calcium and phosphate levels should be monitored regularly if you receive high doses of Potassium Phosphate, because this medicine may lower your blood calcium level and lead to chalky deposits in tissues.

Additional calcium supplements should be provided if you receive high phosphate doses.

If you receive this solution over longer periods (several weeks) it may be necessary to check your blood phosphate level. Then the amount of phosphate excreted in urine over 24 hours will be measured once weekly.

In general, your blood electrolyte (salt) levels should be monitored.

The amount of potassium administered together with the phosphate (1 mmol potassium per 0.6 mmol phosphate) should be taken into account for electrolyte balancing.

When calculating the phosphate supply in intravenous feeding, the amount of phosphate coming with other solutions (also fat emulsions) should be taken into account.

Other medicines and Potassium Phosphate
Tell your doctor or pharmacist if you are taking or using or have recently taken or used any other medicines.

If you are taking certain medicines to strengthen your heart (e.g. digoxin or other *digitalis* glycosides) you should be aware that the effect of these may become weaker if your blood potassium level rises, and the risk of adverse effects (e.g. irregular heartbeat) may become greater if your blood potassium level falls.

Other phosphate-containing medicines may lead to excessively high blood phosphate levels, especially if your kidney function is impaired.

Certain medicines may lead to excessively high blood potassium levels, which may be associated with heart function disorders such as very slow or irregular heartbeat.This group of medicines includes:

- medicines promoting the urine flow that contain triamterene or amiloride or spironolactone
- medicines suppressing the effect of the hormone aldosterone, which is secreted by the adrenal glands
- certain medicines for treatment of high blood pressure (so-called ACE blockers)
- certain medicines to stop the immune response (tacrolimus, ciclosporin)
- medicines for the treatment of inflammations (the "non-steroidal anti-inflammatories")
- certain painkillers
- Suxamethomium (used to relax the muscles during anaesthesia)
- heparin, when used for a long time

The blood levels of certain painkillers (salicylates) may be higher when used together with Potassium Phosphate.

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 for advice before taking any medicine.

Since no sufficient data are available confirming the safety of the use during pregnancy and breast-feeding, Potassium Phosphate should only be given with due caution. Your doctor will only prescribe this medicine for you if he thinks it is essential for your recovery.

Driving and using machines
Potassium Phosphate has no influence on the ability to drive and to use machines.

3. HOW TO USE POTASSIUM PHOSPHATE

This medicine will be given to you by a doctor or other health professional.

Dosage
The doses you will receive are determined according to your requirements for correction of the existing deficit. Thus your basic requirements and your actual salt levels will be taken into account.
The average requirement during intravenous feeding is about 0.3 – 0.5 mmol phosphate per kg body weight per day in adults, corresponding to 0.5 – 0.8 ml of Potassium Phosphate per kg body weight per day.

If the phosphate deficit is severe, higher doses may have to be applied

The maximum potassium dose may be up to 2 – 3 mmol per kg body weight per day.

Use in children

The doses are determined according to the actual blood potassium and phosphate levels.

The average requirement during intravenous feeding is about 0.2 mmol phosphate per kg body weight per day in children above 1 year and 0.5 mmol phosphate per kg body weight per day in children younger than 1 year.

The maximum potassium dose in children may be up to 1 – 3 mmol per kg body weight per day

Administration rate

Not more than 20 mmol potassium per hour in an adult, corresponding to 0.3 mmol per kg body weight per hour.

Method of administration

Intravenous use (administration via a cannula or a thin tube into a vein).

Potassium Phosphate must be diluted before use in a solution for infusion. The potassium concentration in the infusion solution must not exceed 40 mmol/l (corresponding to 24 mmol/l of phosphate). Suitable solutions are e.g. 0.9 percent sodium chloride or 5 percent glucose solutions.

The infusion should be carried out continuously. Use of infusion pumps is advisable.

Utmost care must be taken to avoid spilling of solution into tissue around the vein because this may lead to tissue death, tissue hardening or chalky deposits.

If you received more Potassium Phosphate than you should
Potassium overdose may lead to irregular heartbeat, low blood pressure and increased blood flow to central organs.
Other disorders include nerve and muscle function disturbances like tiredness, states of confusion, unexplained anxiety, weakness or heaviness of limbs, muscle twitching, numbness, breathing problems and paralysis.

Phosphate overdose may lead to kidney damage due to deposition of calcium phosphate, further deposition of calcium phosphate in other tissues (skin, cornea of the eye, lungs) and low blood calcium level (symptoms: convulsions, muscle cramps, trembling, numbness, tingling, pain or weakness in hands or feet; shortness of breath, or troubled breathing) (see also section ”Special care should be taken with Potassium Phosphate ”).

Treatment

Treatment depends on the nature and severity of the disorder. In cases of severe intoxication treatment with artificial kidney may be necessary.

If an overdose occurs you may receive other medicines including:
• calcium gluconate
• glucose
• other agents that decrease the amount of salts in your blood (ion exchangers).

In certain circumstances treatment with artificial kidney may be life-saving.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Normally, the side effects are dose-dependent and are likely to occur only if too much Potassium Phosphate is given or if it is given too rapidly (symptoms see section "If you received more Potassium Phosphate than you should"). Nevertheless, if the product is given according to instruction, the following side effect has been detected.

The possible side effects are listed according to their frequencies, using the following terms:

Very common:	affects more than 1 treated patient of 10
Common	affects 1 to 10 treated patients of 100
Uncommon:	affects 1 to 10 treated patients of 1,000
Rare:	affects 1 to 10 treated patients of 10,000
Very rare:	affects less than 1 treated patient of 10,000
Not known:	cannot be estimated from the available data

Rare: Feeling sick (nausea)

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

5. HOW TO STORE POTASSIUM PHOSPHATE

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

Do not use Potassium Phosphate after the expiry date which is stated on the ampoule label and the outer carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Only to be used if the solution is clear and colourless and if the ampoule is undamaged .The product is supplied in single-use containers. Containers once opened and any unused contents must be discarded after use.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Potassium Phosphate contains

- The active substances are dipotassium phosphate and potassium dihydrogen phosphate

One ampoule (=20ml) of concentrate for solution for infusion contains

Dipotassium phosphate	1.394 g

Potassium dihydrogen phosphate	0.544 g

1 ml contains 1 mmol potassium and 0.6 mmol phosphate

• The other ingredient is
water for injections.

What Potassium Phosphate looks like and contents of the pack
Potassium Phosphate is a concentrate for solution for infusion. This means that it is administered by a vein drip after it has been diluted in an infusion solution.

It is a clear, colourless solution .

It comes in plastic ampoules of 20 ml, made of colourless polyethylene
It is available in packs of 20 x 20 ml ampoules

Marketing authorisation holder and manufacturer
Marketing authorisation holder
B. Braun Medical Limited,
3, Naas Road Industrial Park,
Dublin 12
Republic of Ireland

Manufacturer
B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Germany

This leaflet was last approved in September 2016

The following information is intended for health-care professionals only:
Overdose
Plasma potassium concentrations of 6.5 mmol/l or more are dangerous, concentrations above 8 mmol/l often lethal.

Method of administration
Special attention should be paid to the fact that Potassium Phosphate is only to be injected into the infusion solution with strict sterile precautions immediately before the infusion is set up.
When carrying out phosphate substitution as a part of parental nutrition, account should be taken of the fact that various solutions used for parenteral nutrition (including lipid emulsions) already contain phosphate.

Special Precautions for Disposal and other Handling
Before administration, Potassium Phosphate must be diluted by addition to a suitable infusion solution. Admixture must be carried out under strict sterile precautions immediately before the infusion is set up. The infusion container should then be shaken gently. Infusion solutions should be free of calcium and magnesium. Suitable solutions are e.g. glucose solutions. The

volume of the infusion solution should be chosen so that concentrations of 40 mmol/l of potassium and 24 mmol/l of phosphate in the infusion solution are not exceeded.

Drug interactions, or suddenly occurring acidosis, acute impairment of renal function or other conditions may lead to sudden hyperkalaemia. Symptoms of hyperkalaemia see section “If you received more Potassium Phosphate than you should”.

Sudden discontinuation of potassium administration may be followed by marked hypokalaemia, which may lead to increased toxicity of cardiac glycosides taken concomitantly.

Potassium Phosphate concentrate for solution for infusion is incompatible with solutions containing calcium and magnesium.