SmPC

Country :	Lebanon
Date of approval :	22.06.2009
Procedure :	National

SUMMARY OF PRODUCT CHARACTERISTICS

1- NAME OF THE MEDICINAL PRODUCT
PHOCYTAN, concentrate for solution for infusion.

2- QUALITATIVE AND QUANTITATIVE COMPOSITION
Glucose-1-phosphate disodium tetrahydrate..... ..... 125.4 g.
Water for injectable preparations .....q.s. for .....1000 ml

Glucose: 0.33 mmol/ml
Phosphorus: 10.23 mg/ml
Phosphates: 0.33 mmol/ml
Osmolarity: 1,000 mosmol/l

3- PHARMACEUTICAL FORM
Concentrate for solution for infusion.

4- CLINICAL PARTICULARS

4.1 Therapeutic indications
- Supply of phosphorus by parenteral route, particularly in the course of exclusively parenteral nutrition.

4.2 Posology and method of administration
Infusion by slow intravenous route.
In the course of exclusively parenteral nutrition, the recommended dose is 7.5 to 15 millimoles of phosphorus for an intake of 1,000 non-protein calories.
In the case of correction of hypophosphoraemia, when the parenteral route is necessary, administer 9 to 10 millimoles of phosphorus over a period of 12 hours.
In the absence of any abnormalities in the renal function or blood electrolyte levels, treatment can be continued in 12-hour fractions at the same doses until phosphoraemia of 2 mg/dl or 0.7 mmol/l is obtained.

4.3 Contraindications
This product must not be administered in the following situations:
- severe chronic renal insufficiency,
- hyperphosphoraemia,
- hypercalcaemia because of the risk of calcium precipitation in the soft tissues.

4.4 Special warnings and precautions for use

Warning
HYPEROSMOLAR SOLUTION THAT MUST BE DILUTED BEFORE USE
Take into account the presence of sodium.

Special precautions for use
Monitor the plasma electrolyte concentrations closely and, in particular, the calcium and phosphorus concentrations in the serum, which must be tested every 12 to 24 hours.
Monitoring of the renal function. The dose must be reduced in the event of a change in renal function.

4.5 Interactions with other medicinal products and other forms of interaction

Inadvisable association
+ *IV calcium salts*: physico-chemical incompatibility.

Association to be taken into consideration
+ *Salicylates*: increased excretion of salicylates by alkalinisation of urines.

4.6 Pregnancy and lactation
This product can be used during pregnancy and lactation if necessary.

4.7 Effects on the ability to drive and use machines

Not applicable.

4.8 Undesirable effects
This essentially concerns hyperphosphoraemia, which is rarely observed except in the case of renal insufficiency, acidosis, acromegaly, haemolysis, rhabdomyolysis, tissue destruction or even vitamin D poisoning.
Hyperphosphoraemia can lead to hypercalcaemia that may be severe and result in ectopic tissue calcification, especially in patients who already suffer from hypercalcaemia.

4.9 Overdose
An overdose or an overly fast infusion can lead to hyperphosphoraemia (see section 4.8 “undesirable effects”).
The administration of sodium phosphate in overly large quantities and/or for overly long periods can lead to hydroelectrolyte disturbances (hydrosodium overload).
The treatment of an overdose is the immediate discontinuation of phosphorus and the correction of the hydroelectric disequilibrium.
It may be necessary to take specific measure to lower phosphataemia, such as the oral administration of a phosphate-chelating agent or a renal dialysis.

5- PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

PLASMA SUBSTITUES AND SOLUTION FOR INFUSION / ELECTROLYTES
ATC code: B 05 X

The phosphate ion is the principal anion in the intracellular fluids. The body contains 80% in the divalent form (HPO_4^{2-}) and 20% in the monovalent form ($H_2PO_4^-$).
It is involved in several physiological processes in the body: maintaining intracellular calcium levels, carbohydrate and lipid metabolism, buffer role in the intracellular fluid, cellular metabolism and eliminating H^+ ions in the kidneys.
The normal plasma concentration for phosphate ions is between 0.8 and 1.5 mmol/l.
Approximately 80% of the phosphates present in the body are found in the bones.

5.2 Pharmacokinetic properties
The phosphate ion is eliminated by the kidneys.
The phosphate concentration in the glomerular filtrate is very similar to its concentration in plasma. Filtered phosphate is mainly re-absorbed by the proximal tubule (65 to 80%) while 5 to 10% is re-absorbed by the distal tubule. Re-absorption can reach saturation and attains a plateau when the phosphate concentration in the plasma increases.
Under normal dietary conditions, 15 to 20% of the filtered load is excreted.

5.3 Preclinical safety data
Not applicable.

6- PHARMACEUTICAL PARTICULARS

6.1 Incompatibilities
Calcium salts
Alkaline salts

6.2 Shelf life
2 years.

6.3 Special precautions for storage
Store in the outer primary packaging away from light.

6.4 Nature and contents of container
10-ml ampoule (glass): box of 100
20-ml ampoule (glass): box of 50
20-ml bottle ampoule (glass); box of 10, 25 or 50
50-ml vial (glass); box of 20
100-ml vial (glass); box of 20

6.5 Instructions for use and handling
Not applicable.