PRESCRIBING INFORMATION

SODIUM PHOSPHATES INJECTION USP

P 3 mmol/mL

Electrolyte Replenisher

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ACTION AND CLINICAL PHARMACOLOGY

Phosphorus, in the form of organic and inorganic phosphate, is involved in many significant metabolic and enzyme reactions, in almost all organs and tissues. It participates in bone deposition of calcium, and exerts a modifying influence on the steady state of calcium levels. It plays a significant intracellular role in the synthesis of high energy organic phosphates.

Furthermore, the acid-base equilibrium may be modified, because phosphate ions are buffers on the intracellular fluid and play a primary role in the renal excretion of hydrogen ion. Owing to this relatively low concentration, phosphate contributes relatively little to the buffering capacity of extracellular fluid.

IV infusion of inorganic phosphate may be accompanied by a decrease in the serum level and urinary excretion of calcium.

Pharmacokinetics

Phosphorus is present in plasma and other extracellular fluid, in cell membranes and intracellular fluid, as well as in collagen and bone tissues. Phosphate in the extracellular fluid is primarily in inorganic form, and plasma-levels may vary somewhat with age. The ratio of disodium phosphate and monosodium phosphate in the extracellular fluid is 4:1 (80% : 20%) at the normal pH of 7.4.

The normal plasma levels of phosphate in the adult range between 2.2 and 4.4 mg/dL, with values about 50% higher in babies and 30% higher in children. Levels may vary as much as 2 mg/dL throughout the day, secondary to changes in transcellular distribution.

In general, in adults, about two thirds of the ingested phosphate is absorbed from the bowel, and that which is absorbed from the gut is almost entirely excreted in urine. More than 90% of the phosphate in plasma is filterable, and the bulk is then actively reabsorbed by the proximal tubule. Parathyroid hormone increases the urinary excretion of phosphate by blocking reabsorption, therefore preventing hyperphosphatemia, if the kidney is healthy.

IV infused phosphate not taken up by the tissues is excreted almost entirely in the urine.

INDICATIONS AND CLINICAL USE

Intravenous phosphate is indicated in the presence of severe hypophosphatemia, with clinical manifestations of phosphate depletion such as mental derangements, hemolysis and rhabdomyolysis.

CONTRAINDICATIONS

Phosphate is contraindicated in diseases where high sodium, high phosphate or low calcium may be encountered.

PRECAUTIONS

Use with caution in patients with renal impairment, cirrhosis, cardiac failure, and other edematous or sodium retaining states.

Use with caution in patients with oliguria or anuria.

Plasma-electrolyte concentrations, expecially inorganic phosphate, calcium and sodium, and renal function should be carefully monitored. Diluted solutions must be infused slowly.

ADVERSE REACTIONS

Adverse reactions involve the possibility of combined sodium and phosphate intoxication from overdosage. Phosphate intoxication results in a reduction of serum calcium, and the symptoms are those of hypocalcemic tetany. Hyperphosphatemia usually occurs as a result of renal failure. Sodium excess can lead to accumulation of extracellular fluid (oedema) which may affect cerebral, pulmonary or peripheral circulations.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator 0701E
    Ottawa, Ontario
    K1A 0K9

  Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

DOSAGE AND ADMINISTRATION

Mild hypophosphatemia secondary to redistribution, with plasma phosphate level higher than 2 mg/dL, is transient and requires no treatment. Levels below 1 mg/dL are dangerous and require replacement.

For patients with mild to moderate hypophosphatemia (serum phosphate higher than 1.0 mg/dL in adult), in whom the gastrointestinal tract cannot be utilized, we suggest the following doses of phosphorus to be infused over 6 hours and additional doses guided by serum levels:

- Recent and uncomplicated hypophosphatemia require 0.08 mmol/kg to a maximum of 0.2 mmol/kg.
- Prolonged and multiple causes of hypophosphatemia require 0.16 mmol/kg to a maximum of 0.24 mmol/kg.

In the presence of severe hypophosphatemia with serious clinical manifestations of phosphate depletion, we suggest the following doses of phosphorus to be infused over 4 hours and repeated based on serum levels:

- For serum phosphate levels below 0.5 mg/dL, administer 0.5 mmol/kg.
- For serum phosphate levels below 0.5 to 1 mg/dL, administer 0.25 mmol/kg.

Monitor serum inorganic phosphate, calcium and sodium levels every 4 to 6 hours. Amount infused

has to be adjusted accordingly to the measured levels. Change to oral dosing when serum phosphate exceeds 2 mg/dL.

Sodium phosphates solution must be diluted before use, and infused slowly.

OVERDOSAGE

For management of a suspected drug overdose, contact your regional Poison Control Centre.

STORAGE AND STABILITY

Store between 15 and 30ºC. Protect from light.

DOSAGE FORMS, COMPOSITION AND PACKAGING

Each mL contains: monobasic sodium phosphate monohydrate 276 mg and dibasic sodium phosphate heptahydrate 268 mg to provide 3 mmol phosphorus and 4 mmol (4 mEq) sodium. Provides 7,0 mOsm/mL.

Dilute prior to administration. Preservative free.

Single use vials of 10 mL, boxes of 10.

The chlorobutyl rubber stopper is not made with natural rubber latex.

REFERENCES

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