PRESCRIBING INFORMATION

POTASSIUM PHOSPHATES INJECTION, USP

(3 mmol Phosphorus / mL and 4.4 mEq Potassium / mL)
7.4 mOsmol / mL

Sterile Solution

For Intravenous Infusion After Dilution

Electrolyte Solution

ATC code: B05XA06

Fresenius Kabi Canada Ltd.
165 Galaxy Blvd, Suite 100
Toronto, ON M9W 0C8

Date of Preparation**:**
November 24, 2020

Submission Control No: 235443

PRESCRIBING INFORMATION

POTASSIUM PHOSPHATES INJECTION, USP

(3 mmol Phosphorus / mL and 4.4 mEq Potassium / mL)

7.4 mOsmol / mL

DESCRIPTION

Potassium Phosphates Injection, USP is a sterile, preservative free, nonpyrogenic, concentrated solution containing a mixture of mono- and dibasic potassium phosphate in Water for Injection. It must be diluted prior to administration.

Each mL of the solution consists of two phosphate salts provided as follows:

Ingredients	Phosphate	Potassium
Monobasic Potassium Phosphate – 224 mg	285 mg (3 mmol)	170 mg (4.4 mEq)
Dibasic Potassium Phosphate – 236 mg		

The solution contains no bacteriostatic agent or other preservatives.

The solution is intended to provide phosphate ion (PO_4^{-3}) for addition to large volume infusion fluids for intravenous use. Unused portions should be discarded.

CLINICAL PHARMACOLOGY

Phosphorus in the form of organic and inorganic phosphate has a variety of important biochemical functions in the body and is involved in many significant metabolic and enzyme reactions in almost all organs and tissues. It exerts a modifying influence on the steady state of calcium levels, a buffering effect on acid-base equilibrium and a primary role in the renal excretion of hydrogen ion.

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. This buffer ratio varies with the pH, but owing to its relatively low concentration, it contributes little to the buffering capacity of the extracellular fluids.

Phosphate, present in large amounts in erythrocytes and other tissue cells, plays a significant intracellular role in the synthesis of high energy organic phosphates.

Hypophosphatemia should be avoided during periods of total parenteral nutrition, or other lengthy periods of intravenous infusions. Serum phosphate levels should be regularly monitored, and appropriate amounts of phosphate should be added to the infusions to maintain normal serum phosphate levels. Intravenous infusion of inorganic phosphate may be accompanied by a decrease in the serum level and urinary excretion of calcium. Intravenously infused phosphate not taken up by the tissues is excreted almost entirely in the urine.

INDICATIONS AND USAGE

Potassium Phosphates Injection, USP is indicated as a source of phosphate, for addition to large volume intravenous fluids to prevent or correct hypophosphatemia in patients with restricted or no oral intake. It is also useful as an additive for preparing specific intravenous fluid formulas when the needs of the patient cannot be met by standard electrolyte or nutrient solutions.

CONTRAINDICATIONS

Potassium Phosphates Injection, USP is contraindicated in diseases where high potassium, high phosphate or low calcium levels may be encountered.

WARNINGS

Potassium Phosphates Injection, USP must be diluted before use.

To avoid potassium or phosphate intoxication, infuse solutions containing potassium phosphates slowly. In patients with severe renal or adrenal insufficiency, administration of potassium phosphates may cause potassium intoxication, infusing high concentrations of phosphate may cause hypocalcemia, and calcium levels should be monitored.

This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions which contain aluminum. Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 mcg per kg per day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration of TPN products and of the lock-flush solutions used in their administration.

PRECAUTIONS

Phosphate replacement therapy with Potassium Phosphates Injection, USP should be guided primarily by the serum inorganic phosphate level and the limits imposed by the accompanying potassium (K^+) ion.

High plasma concentrations of potassium may cause death through cardiac depression, arrhythmias or arrest.

Use with caution in the presence of cardiac disease, particularly in digitalized patients or in the presence of renal disease.

ADVERSE REACTIONS

Adverse reactions involve the possibility of combined potassium and phosphate intoxication from overdosage. The signs and symptoms of potassium intoxication include paresthesias of the extremities, flaccid paralysis, listlessness, mental confusion, weakness and heaviness of the legs, hypotension, cardiac arrhythmias, heartblock, electrocardiographic abnormalities such as disappearance of P waves, spreading and slurring of the QRS complex with development of a biphasic curve and cardiac arrest. Phosphate intoxication results in a reduction of serum calcium, and the symptoms are those of hypocalcemic tetany. See WARNINGS.

OVERDOSAGE

In the event of overdosage, discontinue infusions containing potassium phosphates immediately, and institute corrective therapy to restore depressed serum calcium and to reduce elevated serum potassium levels.

Parenteral drug products should be inspected visually for particulate matter and discolouration prior to administration, whenever solution and container permit.

DOSAGE AND ADMINISTRATION

Potassium Phosphates Injection, USP, is administered intravenously only after dilution in a larger volume of fluid. The dose and rate of administration are dependent upon the individual needs of the patient. Serum potassium, inorganic phosphorus and calcium levels should be monitored as a guide to dosage.

Withdraw the calculated volume aseptically and transfer to appropriate intravenous fluid to provide the desired number of millimoles (mmol) of phosphorus and milliequivalents (mEq) of potassium (K^+).

AVAILABILITY OF DOSAGE FORMS

Product Number	Volume Fill	Vial Size	Strength	Phosphorus/mL	Potassium/mL
C8615P	15 mL	30 mL (glass vial)	45 mmol Phosphorus and 66 mEq Potassium per 15 mL	285 mg	170 mg
C8650	50 mL	50 mL (glass vial)	150 mmol Phosphorus and 220 mEq Potassium per 50 mL	285 mg	170 mg
C860529	5 mL	10 mL (plastic vial)	15 mmol Phosphorus and 22 mEq Potassium per 5 mL	285 mg	170 mg
C860539	15 mL	20 mL (plastic vial)	45 mmol Phosphorus and 66 mEq Potassium per 15 mL	285 mg	170 mg
C860569	50 mL	50 mL (plastic vial)	150 mmol Phosphorus and 220 mEq Potassium per 50 mL	285 mg	170 mg

The format 5mL (C860529), 15mL (C860539) and 50mL (C860569) are packaged in Polypropylene plastic clear vials of 20mm of size of 10mL, 20mL and 50mL closed with 20mm gray, chlorobutyl latex free rubber stoppers and sealed with light green aluminum flip cap.

The products do not contain a bacteriostatic agent or other preservatives. They are packaged 25 vials per tray. Any unused portion should be discarded.

The drug product should be visually inspected before use, do not use if it is not essentially free from visible particulates, or the containers are cracked and seals are defective.

The Potassium Phosphate Injection, USP in the glass vials contains no more than 32,800 mcg/L of aluminum. The Potassium Phosphate Injection, USP in the plastic vials contains no more than 2000 mcg/L of aluminum.

Store at 15 °C to 30 °C.

This Prescribing Information is prepared by:

Fresenius Kabi Canada Ltd.
165 Galaxy Blvd, Suite 100
Toronto, ON M9W 0C8
Questions or concerns? 1-877-821-7724

Date of preparation: November 24, 2020