POTASSIUM PHOSPHATES
Injection, USP
3 mM P/mL and 4.4 mEq K^+/mL
FOR ADDITIVE USE ONLY AFTER DILUTION IN I.V. FLUIDS
Fliptop Vial
Rx Only

DESCRIPTION

Potassium Phosphates Injection, USP 3 mM P/mL (millimoles/mL) is a sterile, nonpyrogenic, *concentrated solution* containing a mixture of mono- and dibasic potassium phosphate in water for injection.

The solution is administered after dilution by the intravenous route as an electrolyte replenisher. It must not be administered undiluted.

Each milliliter contains 224 mg of monobasic potassium phosphate, anhydrous and 236 mg of dibasic potassium phosphate, anhydrous. One mM of phosphorus weighs 31 mg and the product provides 93 mg (approximately 3 mM) of phosphorus/mL, plus 170.3 mg (4.4 mEq) of potassium/mL. **Note:** 1 mM P=1 mM PO_4.

It contains no bacteriostat, antimicrobial agent or added buffer. The osmolar concentration is 7.4 mOsmol/mL (calc.). The solution is intended as an alternative to sodium phosphate to provide phosphorus for addition to large volume infusion fluids for intravenous use.

Monobasic Potassium Phosphate, NF (monopotassium phosphate), anhydrous is chemically designated KH_2PO_4, colorless crystals or white granular powder freely soluble in water.

Dibasic Potassium Phosphate, USP (dipotassium phosphate), anhydrous is chemically designated K_2HPO_4, white granules very soluble in water.

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.

Phosphorus 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 to 1 (80% to 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 fluid.

Phosphorus, present in large amounts in erythrocytes and other tissue cells, plays a significant intracellular role in the synthesis of high energy organic phosphates. It has been shown to be essential to maintain red cell glucose utilization, lactate production and the concentration of both erythrocyte adenosine triphosphate (ATP) and 2,3 diphosphoglycerate (DPG) and must be deemed as important to other tissue cells. Hypophosphatemia should be avoided during periods of total parenteral nutrition or other lengthy periods of intravenous infusions. Serum phosphorus levels should be regularly monitored and appropriate amounts of phosphorus should be added to the infusions to maintain normal serum phosphorus levels. Intravenous infusion of inorganic phosphorus may be accompanied

by a decrease in the serum level and urinary excretion of calcium. The normal level of serum inorganic phosphorus is 3.0 to 4.5 mg/100 mL in adults; 4.0 to 7.0 mg/100 mL in children.

Potassium is the principal intracellular cation; it helps transport dextrose across the cell membrane and contributes to normal renal function. It has been suggested that 40 mEq potassium be used for every 1000 kcal of dextrose supplied to patients receiving total parenteral nutrition and 12 to 15 mM phosphorus for each 250 g of dextrose.

Intravenously infused phosphorus not taken up by the tissues is excreted almost entirely in the urine. Plasma phosphorus is believed to be filterable by the renal glomeruli and the major portion of filtered phosphorus (greater than 80%) is actively reabsorbed by the tubules. Many modifying influences tend to alter the amount excreted in the urine.

INDICATIONS AND USAGE

Potassium Phosphates Injection, USP, 3 mM P/mL is indicated as a source of phosphorus, 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. The concomitant amount of potassium (K^+ 4.4 mEq/mL) must be calculated into total electrolyte dose of such prepared solutions.

Safety has not been established for parenteral nutrition in pediatric patients due to the risk of aluminum toxicity. (See WARNINGS)

CONTRAINDICATIONS

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

WARNINGS

Potassium Phosphates Injection, USP, 3 mM P/mL must be diluted before use.

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

Solutions which contain potassium ions should be used with great care, if at all, in patients with hyperkalemia, severe renal failure and in conditions in which potassium retention is present.

In patients with diminished renal function, administration of solutions containing potassium ions may result in potassium retention.

Aluminum Toxicity

Potassium Phosphates Injection is not recommended in pediatric patients due to the risk of aluminum toxicity.

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.

Patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

PRECAUTIONS

Do not administer unless solution is clear and seal is intact. Discard unused portion.

Phosphorus replacement therapy with potassium phosphate should be guided primarily by the serum inorganic phosphorus 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.

***Pregnancy*:** Animal reproduction studies have not been conducted with potassium phosphate. It is also not known whether potassium phosphate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Potassium phosphate should be given to a pregnant woman only if clearly needed.

ADVERSE REACTIONS

Adverse reactions involve the possibility of combined potassium and phosphorus 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, heart block, electrocardiographic abnormalities such as disappearance of P waves, spreading and slurring of the QRS complex with development of a biphasic curve and cardiac arrest.

Phosphorus 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 phosphate immediately and institute corrective therapy to restore depressed serum calcium and to reduce elevated serum potassium levels. See WARNINGS, PRECAUTIONS and ADVERSE REACTIONS.

DOSAGE AND ADMINISTRATION

Potassium Phosphates Injection, USP 3 mM P/mL 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. Using aseptic technique, all or part of the contents of one or more vials may be added to other intravenous fluids to provide any desired number of millimoles (mM) of phosphorus.

In adult patients receiving TPN (total parenteral nutrition), a dose of 12 to 15 mM phosphorus is recommended for each 500 mL of 50% Dextrose Injection, USP administered. The amount of potassium which accompanies the addition of phosphorus as potassium phosphate also should be kept in mind and if necessary, serum potassium levels and/or electrocardiographic changes should be monitored.

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

HOW SUPPLIED

Potassium Phosphates Injection, USP is supplied as follows:

Unit of Sale	Concentration	Unit of Use
NDC 0409-7295-01 Tray containing 25 vials	45 mM (3 mM P/mL) containing 66 mEq K^+ (4.4 mEq/mL)	NDC 0409-7295-11 15 mL Single-dose Fliptop Vial

Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.]

Distributed by Hospira, Inc., Lake Forest, IL 60045 USA

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LAB-1052-3.0

Revised: 03/2023