

POTASSIUM PHOSPHATES INJECTION, USP

(3 mM PHOSPHORUS/mL 4.4 mEq POTASSIUM/mL)

Osmolarity 7.4 mOsmol/mL

Rx Only



**CAUTION: FOR INTRAVENOUS USE ONLY
MUST BE DILUTED PRIOR TO ADMINISTRATION**

DESCRIPTION: Potassium Phosphates Injection, USP is a sterile, nonpyrogenic, concentrated solution containing a mixture of monobasic 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:

Ingredient(s)	Phosphorus	Potassium
Monobasic Potassium Phosphate - 224 mg Anhydrous	93 mg	170 mg
	or	or
Dibasic Potassium Phosphate - 236 mg Anhydrous	3 mM	4.4 mEq

The solution contains no bacteriostatic agent or other preservative.

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. 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 4:1 (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.

Phosphorus, 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 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/dL in adults and 4.0 to 7.0 mg/dL in children. Intravenously infused phosphorus not taken up by the tissues is excreted almost entirely in the urine.

Potassium is the principal intracellular cation. It helps transport dextrose across the cell membrane and contributes to normal renal function.

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 (4.4 mEq/mL) must be calculated into total electrolyte content of such prepared solutions.

CONTRAINDICATIONS: Potassium Phosphates Injection is contraindicated in diseases where high potassium, high phosphorus or low calcium levels may be encountered.

WARNINGS: Potassium Phosphates Injection must be diluted and thoroughly mixed before use.

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

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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.

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/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: Phosphorus replacement therapy with potassium phosphates should be guided primarily by the serum inorganic phosphorus levels and the limits imposed by the accompanying potassium (K^+) ion. Frequent monitoring of serum calcium and potassium as well as renal function is recommended.

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: Teratogenic Effects. *Pregnancy Category C.* Animal reproduction studies have not been conducted with Potassium Phosphates Injection. It is also not known whether Potassium Phosphates Injection can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Potassium Phosphates Injection 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**.

DOSAGE AND ADMINISTRATION: Potassium Phosphates Injection 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 (mM) of phosphorus and milliequivalents (mEq) of potassium.

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. (See **WARNINGS**, **PRECAUTIONS** and **ADVERSE REACTIONS**).

Parenteral drug products should be inspected visually for particulate matter and discoloration, whenever solution and container permit.

HOW SUPPLIED: Potassium Phosphates Injection, USP 3mM Phosphorus/mL, 4.4 mEq Potassium/mL

NDC 0517-2305-25	5 mL Single Dose Vial	packed in boxes of 25
NDC 0517-2315-25	15 mL Single Dose Vial	packed in boxes of 25
NDC 0517-2350-25	50 mL Single Dose Vial	packed in boxes of 25

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) (See USP Controlled Room Temperature).

These products do not contain a bacteriostatic agent or other preservatives. Any unused portion should be discarded.

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