

Potassium phosphates injection is for *intravenous infusion only after dilution or admixing*. The maximum initial or single dose of Potassium phosphates injection in intravenous fluids to correct hypophosphatemia is phosphorus 45 mmol (potassium 66 mEq). The recommended infusion rate for administration through a peripheral venous catheter is approximately phosphorus 6.8 mmol/hour (potassium 10 mEq/hour). Continuous electrocardiographic (ECG) monitoring is recommended for higher infusion rates [see *Dosage and Administration* (2.1, 2.2)].

5.2 Pulmonary Embolism due to Pulmonary Vascular Precipitates

Pulmonary vascular emboli and pulmonary distress related to precipitates in the pulmonary vasculature have been described in patients receiving admixed products containing calcium and phosphate or parenteral nutrition. The cause of precipitate formation has not been determined in all cases; however, in some fatal cases, pulmonary emboli occurred as a result of calcium phosphate precipitates. Precipitation has occurred following passage through an in-line filter; *in vivo* precipitate formation may also have occurred. If signs of pulmonary distress occur, stop the parenteral nutrition infusion and initiate a medical evaluation. In addition to inspection of the solution [see *Dosage and Administration* (2.3)], the infusion set and catheter should also periodically be checked for precipitates.

5.3 Hyperkalemia

Potassium phosphates injection may increase the risk of hyperkalemia, including life-threatening cardiac events, especially when administered in excessive doses, undiluted or by rapid intravenous infusion [see *Warnings and Precautions* (5.1)]. Patients with severe renal impairment and end stage renal disease are at increased risk of developing life-threatening hyperkalemia, when administered intravenous potassium [see *Contraindications* (4)]. Other patients at increased risk of hyperkalemia include those with severe adrenal insufficiency or treated concurrently with other drugs that cause or increase the risk of hyperkalemia [see *Drug Interactions* (7.1)]. Patients with cardiac disease may be more susceptible to the effects of hyperkalemia.

Consider the amount of potassium from all sources when determining the dose of Potassium phosphates injection and do not exceed the maximum age-appropriate recommended daily amount of potassium. In patients with moderate renal impairment (eGFR ≥30 mL/min/1.73 m² to <60 mL/min/1.73 m²), start at the low end of the dose range and monitor serum potassium, phosphorus, calcium, and magnesium concentrations [see *Dosage and Administration* (2.2, 2.4), *Use in Specific Populations* (8.6)].

When administering Potassium phosphates injection in intravenous fluids to correct hypophosphatemia, check the serum potassium concentration prior to administration. If the potassium concentration is 4 mEq/dL or more, do not administer Potassium phosphates injection and use an alternative source of phosphorus [see *Dosage and Administration* (2.1)].

The maximum initial or single dose of Potassium phosphates injection in intravenous fluids to correct hypophosphatemia is phosphorus 45 mmol (potassium 66 mEq). The recommended infusion rate of potassium through a peripheral venous catheter is 10 mEq/hour. Continuous electrocardiographic (ECG) monitoring is recommended for higher infusion rates of potassium [see *Dosage and Administration* (2.2)].

5.4 Hyperphosphatemia and Hypocalcemia

Hyperphosphatemia can occur with intravenous administration of potassium phosphates, especially in patients with renal impairment. Hyperphosphatemia can cause the formation of insoluble calcium phosphorus products with consequent hypocalcemia, neurological irritability with tetany, nephrocalcinosis with acute kidney injury and more rarely, cardiac irritability with arrhythmias.

Obtain serum calcium concentrations prior to administration and normalize the calcium before administering Potassium phosphates injection. Potassium phosphates injection is contraindicated in patients with hyperphosphatemia and/or hypocalcemia [see *Contraindications* (4)].

Monitor serum phosphorus and calcium concentrations during treatment with Potassium phosphates injection [see *Dosage and Administration* (2.2, 2.4)].

5.5 Aluminum Toxicity

Potassium phosphates injection contains aluminum that may be toxic.

Aluminum may reach toxic levels with prolonged parenteral administration in patients with renal impairment. Preterm infants are particularly at risk for aluminum toxicity because their kidneys are immature, and they require large amounts of calcium and phosphate containing solutions, which also contain aluminum.

Patients with renal impairment, including preterm infants, who receive greater than 4 to 5 mcg/kg/day of parenteral aluminum can accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

Exposure to aluminum from Potassium phosphates injection is no more than 0.6 mcg/kg/day when patients are administered the recommended dosage [see *Dosage and Administration* (2.4), *Description* (11)].

When prescribing Potassium phosphates injection for use in parenteral nutrition solutions containing other small volume parenteral products, the total daily patient exposure to aluminum from the admixture should be considered and maintained at no more than 5 mcg/kg/day [see *Use in Specific Populations* (8.4)].

5.6 Hypomagnesemia

Intravenous infusion of phosphate has been reported to cause a decrease in serum magnesium (and calcium) concentrations when administered to patients with hypercalcemia and diabetic ketoacidosis. Monitor serum magnesium concentrations during treatment.

5.7 Vein Damage and Thrombosis

Potassium phosphates injection must be diluted and administered in intravenous fluids or used as an admixture in parenteral nutrition. It is not for direct intravenous infusion. The infusion of hypertonic solutions into a peripheral vein may result in vein irritation, vein damage, and/or thrombosis. The primary complication of peripheral administration is venous thrombophlebitis, which manifests as pain, erythema, tenderness or a palpable cord. Remove the catheter as soon as possible and initiate appropriate medical treatment if thrombophlebitis develops.

When administered peripherally in intravenous fluids to correct hypophosphatemia, a generally recommended maximum concentration is phosphorus 6.8 mmol/100 mL (potassium 10 mEq/100 mL) [see *Dosage and Administration* (2.1)]

Parenteral nutrition solutions with an osmolality of 900 mOsmol/L or greater must be infused through a central catheter [see *Dosage and Administration* (2.3)].

5.8 Laboratory Monitoring

Monitor serum phosphorus, potassium, calcium and magnesium concentrations during treatment [see *Dosage and Administration* (2.2, 2.4)].

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Aluminum Toxicity [see *Warnings and Precautions* (5.5)]
- Hypomagnesemia [see *Warnings and Precautions* (5.6)]
- Vein Damage and Thrombosis [see *Warnings and Precautions* (5.7)]

The following adverse reactions in Table 5 have been reported in clinical studies or postmarketing reports in patients receiving intravenously administered potassium phosphates. Because some of these reactions were reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

TABLE 5: Adverse Reactions Reported in Clinical Studies or Postmarketing Reports with Intravenous Potassium Phosphates

System Organ Class	Adverse Reactions
<i>Metabolism and Nutrition Disorders</i>	pulmonary embolism due to pulmonary vascular precipitates [see <i>Warnings and Precautions</i> (5.2)], hyperkalemia [see <i>Warnings and Precautions</i> (5.3)], hyperphosphatemia [see <i>Warnings and Precautions</i> (5.4)], hypocalcemia [see <i>Warnings and Precautions</i> (5.5)], hypovolemia, and osmotic diuresis
<i>Cardiac Disorders</i>	hypotension, arrhythmia, heart block, cardiac arrest, bradycardia, chest pain, ECG changes [see <i>Warnings and Precautions</i> (5.1)], and edema
<i>Respiratory, Thoracic, and Mediastinal Disorders</i>	dyspnea [see <i>Warnings and Precautions</i> (5.2)]
<i>Renal and Urinary Disorders</i>	acute phosphate nephropathy (i.e., nephrocalcinosis with acute kidney injury), decreased urine output, and transition to chronic kidney disease [see <i>Warnings and Precautions</i> (5.4)]
<i>Gastrointestinal Disorders</i>	diarrhea, stomach pain
<i>Musculoskeletal and Connective Tissue Disorders</i>	weakness
<i>Nervous System Disorders</i>	confusion, lethargy, paralysis, paresthesia

7 DRUG INTERACTIONS

7.1 Other Products that Increase Serum Potassium

Administration of Potassium phosphates injection to patients treated concurrently or recently with products that increase serum potassium (e.g., potassium-sparing diuretics, ACE inhibitors, angiotensin II receptor antagonists, digoxin, or the immunosuppressants tacrolimus and cyclosporine) increases the risk of severe and potentially fatal hyperkalemia, in particular in the presence of other risk factors for hyperkalemia [see *Warnings and Precautions* (5.3)]. Avoid use of Potassium phosphates injection in patients receiving such products. If use cannot be avoided, closely monitor serum potassium concentrations [see *Dosage and Administration* (2.2, 2.4)].

8 USES IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Administration of the recommended dose of Potassium phosphates injection is not expected to cause major birth defects, miscarriage, or adverse maternal or fetal outcomes. Animal reproduction studies have not been conducted with Potassium phosphates injection.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Clinical Considerations

Disease-associated Maternal and/or Embryo-Fetal Risk

Phosphorus is an essential mineral element. Parenteral supplementation with potassium phosphates should be considered if a pregnant woman's requirements cannot be fulfilled by oral or enteral intake.

8.2 Lactation

Risk Summary

Phosphorus and potassium are present in human milk. Administration of the recommended dose of Potassium phosphates injection is not expected to cause harm to a breastfed infant. There is no information on the effects of potassium phosphates on milk production. The development and health benefits of breastfeeding should be considered along with the mother's clinical need for Potassium phosphates injection and any potential adverse effects on the breastfed child from Potassium phosphates injection or from underlying maternal condition.

8.4 Pediatric Use

Safety and effectiveness of Potassium phosphates injection have been established in pediatric patients as a source of phosphorus:

- in intravenous fluids to correct hypophosphatemia when oral or enteral replacement is not possible, insufficient, or contraindicated.
- for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated.

Because of immature renal function, preterm infants receiving prolonged parenteral nutrition treatment with Potassium phosphates injection may be at higher risk of aluminum toxicity. [see *Warnings and Precautions* (5.5)].

8.5 Geriatric Use

In general, dose selection of Potassium phosphates injection for an elderly patient should be cautious, starting at the low end of the dosing range because of the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. It may be useful to monitor renal function during treatment [see *Use in Specific Populations* (8.6)].

8.6 Renal Impairment

Potassium and phosphorus are known to be substantially excreted by the kidney and the risk of adverse reactions to Potassium phosphates injection may be greater in patients with impaired renal function [see *Warnings and Precautions* (5.3, 5.4, 5.5)].

Potassium phosphates injection is contraindicated due to the risk of hyperkalemia in patients with severe renal impairment (eGFR less than 30 mL/min/1.73 m²) or end stage renal disease [see *Contraindications* (4)].

In patients with moderate renal impairment (eGFR ≥ 30 mL/min/1.73 m² to < 60 mL/min/1.73 m²), start at the low end of the dosage range and monitor serum potassium, phosphorus, calcium, and magnesium concentrations [see *Dosage and Administration* (2.2, 2.4)].

10 OVERDOSAGE

Hyperphosphatemia

Administration of excessive doses of intravenous potassium phosphates in intravenous fluids as a single dose ranging from approximately 50 to 270 mmol phosphorus and/or at rapid infusion rates (over 1 to 3 hours) has resulted in death, cardiac arrest, cardiac arrhythmia (including QT prolongation), hyperkalemia, hyperphosphatemia, seizures, and tetany.

Hyperphosphatemia is particularly a risk in patients with renal failure. Hyperphosphatemia leads in turn to hypocalcemia, which may be severe, and to ectopic calcification, particularly in patients with initial hypercalcemia. Tissue calcification may cause hypotension and organ damage and result in acute renal failure.

Hyperkalemia

Excessive administration of phosphates given as potassium salts may also cause hyperkalemia.

Manifestations of hyperkalemia include:

- Disturbances in cardiac conduction and arrhythmias, including bradycardia, heart block, asystole, ventricular tachycardia, ventricular fibrillation
- Hypotension
- Muscle weakness including paresthesia, muscular and respiratory paralysis

Management

In the event of overdosage, discontinue infusions containing potassium phosphates immediately and institute general supportive measures, including ECG monitoring, laboratory monitoring, and correction of serum electrolyte concentrations, especially potassium, phosphorus, calcium, and magnesium.

11 DESCRIPTION

Potassium phosphates injection, USP, a phosphorus replacement product containing phosphorus 3 mmol/mL and potassium 4.4 mEq/mL. It is a sterile, non-pyrogenic, concentrated solution containing a mixture of monobasic potassium phosphate and dibasic potassium phosphate in water for injection. It is supplied as a 5 mL and 15 mL single-dose vials and a 50 mL Pharmacy Bulk Package vial.

Monobasic Potassium Phosphate is chemically designated KH₂PO₄, molecular weight 136.09, white, odorless crystals or granules freely soluble in water.

Dibasic Potassium Phosphate is chemically designated K₂HPO₄, molecular weight 174.18, colorless or white granular salt freely soluble in water.

Each mL contains 224 mg of monobasic potassium phosphate and 236 mg of dibasic potassium phosphate.

Each mL contains 3 mmol phosphorus (equivalent to 93 mg phosphorus) and 4.4 mEq potassium (equivalent to 170 mg of potassium). Note: 1 mmol of phosphorus is equal to 1 mmol phosphate. The pH is 6.0 to 7.0.

This product contains no more than 900 mcg/L of aluminum [see *Warnings and Precautions* (5.5)].

The osmolality is 7.4 mOsmol/mL (calc).

The solution is administered after dilution or admixing by the intravenous route.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Phosphorus in the form of organic and inorganic phosphate has a variety of biochemical functions in all organs and tissues, including critical roles in nucleic acid structure, energy storage and transfer, cell signaling, cell membrane composition and structure, acid-base balance, mineral homeostasis and bone mineralization.

12.3 Pharmacokinetics

Distribution

Approximately 85% of serum phosphates is free and ultra-filterable and 15% is protein-bound.

Elimination

Intravenously infused phosphates not taken up by the tissues are excreted almost entirely in the urine. Serum 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.

16 HOW SUPPLIED/STORAGE AND HANDLING

Potassium phosphates injection, USP is a clear and colorless solution supplied as phosphorus 3 mmol/mL and potassium 4.4 mEq/mL as shown:

Unit of Sale	Strength	Each
NDC 65145-194-25 Carton containing 25 units	Phosphorus 15 mmol/5 mL and Potassium 22 mEq/5 mL	NDC 65145-194-01 5 mL single dose, plastic vial
NDC 65145-195-25 Carton containing 25 units	Phosphorus 45 mmol/15 mL and Potassium 66 mEq/15 mL	NDC 65145-195-01 15 mL single dose, plastic vial
NDC 65145-196-25 Carton containing 25 units	Phosphorus 150 mmol/50 mL and Potassium 220 mEq/50 mL	NDC 65145-196-01 50 mL fill Pharmacy Bulk Package, plastic vial.

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

Pharmacy Bulk Package vial: Discard within 4 hours of initial entry [see *Dosage and Administration* (2.3)].

For storage of admixed solution see *Dosage and Administration* 2.1, 2.3.

17 PATIENT COUNSELING INFORMATION

Inform patients, caregivers or home healthcare providers of the following risks of Potassium phosphates injection:

- Serious Cardiac Adverse Reactions with Undiluted, Bolus or Rapid Intravenous Administration [see *Warnings and Precautions* (5.1)]
- Pulmonary Embolism due to Pulmonary Vascular Precipitates [see *Warnings and Precautions* (5.2)]
- Hyperkalemia [see *Warnings and Precautions* (5.3)]
- Hyperphosphatemia and Hypocalcemia [see *Warnings and Precautions* (5.4)]
- Aluminum toxicity [see *Warnings and Precautions* (5.5)]
- Hypomagnesemia [see *Warnings and Precautions* (5.6)]
- Vein Damage and Thrombosis [see *Warnings and Precautions* (5.7)]

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