POTASSIUM PHOSPHATES- potassium phosphates in sodium chloride injection
Amneal Pharmaceuticals LLC

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use POTASSIUM PHOSPHATES IN SODIUM CHLORIDE INJECTION safely and effectively. See full prescribing information for POTASSIUM PHOSPHATES IN SODIUM CHLORIDE INJECTION.

POTASSIUM PHOSPHATES IN SODIUM CHLORIDE injection, for intravenous use
Initial U.S. Approval: 1983

INDICATIONS AND USAGE

Potassium Phosphates in Sodium Chloride Injection is a phosphorus replacement product indicated as a source of phosphorus to correct hypophosphatemia in adults and pediatric patients who weigh 40 kg or greater when oral or enteral replacement is not possible, insufficient or contraindicated. (1)

DOSAGE AND ADMINISTRATION

Important Preparation Instructions

- Do NOT dilute prior to administration (2.1)
- Use this potassium phosphates in sodium chloride injection product only in patients who require the entire 15 mmoL phosphorus dose (potassium 22 mEq) and not any fraction thereof. Otherwise, consider an alternative formulation of potassium phosphate. (2.1)

Important Administration Instructions

- Potassium Phosphates in Sodium Chloride Injection is only for administration to a patient with a serum potassium concentration less than 4 mEq/dL; otherwise, use an alternative source of phosphorus. (2.2)
- Use of this potassium phosphates in sodium chloride injection product increases the risk of hyperkalemia in patients weighing less than 40 kg, including life threatening cardiac events. (5.3)
- See full prescribing information for important administration instructions. (2.2)

Recommended Dosage

- This product contains phosphorus 15 mmol and potassium 22 mEq (phosphorus 0.06 mmol/mL and potassium 0.088 mEq/mL). (2.3)
- Monitor serum phosphorus, potassium, calcium and magnesium concentrations. (2.3)
- See full prescribing information for recommendations on initial or single dosing, repeated dosing, concentration and infusion rate. (2.1, 2.2, 2.3)

DOSAGE FORMS AND STRENGTHS

Injection:

- Phosphorus 15 mmol/250 mL (0.06 mmol/mL) and Potassium 22 mEq/250 mL (0.088 mEq/mL) clear, colorless solution filled in a single-dose intravenous infusion bag. (3)

CONTRAINDICATIONS

- hyperkalemia. (4)
- hyperphosphatemia. (4)
- hypercalcemia or significant hypocalcemia. (4)
- severe renal impairment (eGFR less than 30 mL/min/1.73 m^2) or end stage renal disease. (4)

WARNINGS AND PRECAUTIONS

- Serious Cardiac Adverse Reactions with Rapid Intravenous Administration: Do NOT dilute prior to administration; do not exceed the recommended infusion rate. Continuous electrocardiographic (ECG) monitoring may be needed during infusion. (2.2, 5.1)
- Pulmonary Embolism due to Pulmonary Vascular Precipitates: If signs of pulmonary distress occur, stop the infusion and initiate a medical evaluation. (5.2)
- Hyperkalemia: Increased risk in patients with renal impairment, severe adrenal insufficiency, or treated with drugs that increase potassium. Patients with cardiac disease may be more susceptible. Do not exceed the maximum daily amount of potassium or the recommended infusion rate. Continuous ECG monitoring may be needed during infusion. (5.3, 7.1)
- Hyperphosphatemia and Hypocalcemia: Monitor serum phosphorus and calcium concentrations during

and following infusion. (5.4)
- Hypomagnesemia: Reported in patients with hypercalcemia and diabetic ketoacidosis. Monitor serum magnesium concentrations during treatment. (5.5)
- Vein Damage and Thrombosis: Infuse concentrated or hypertonic solutions through a central catheter. (2.1, 2.3, 5.6)

ADVERSE REACTIONS

Adverse reactions include hyperkalemia, hyperphosphatemia, hypocalcemia, and hypomagnesemia. (6)
To report SUSPECTED ADVERSE REACTIONS, contact Amneal Pharmaceuticals at 1-877-835-5472 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

Use of Other Medications that Increase Potassium: Avoid use in patients receiving such products. If use cannot be avoided, closely monitor serum potassium concentrations. (5.3, 7.1)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 7/2024

FULL PRESCRIBING INFORMATION: CONTENTS*

17 PATIENT COUNSELING INFORMATION

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Potassium Phosphates in Sodium Chloride Injection is indicated as a source of phosphorus to correct hypophosphatemia in adults and pediatric patients who weigh 40 kg or greater when oral or enteral replacement is not possible, insufficient, or contraindicated.

2 DOSAGE AND ADMINISTRATION

2.1 Important Preparation Instructions

- Potassium Phosphates in Sodium Chloride Injection is for *intravenous infusion* into a central or peripheral vein. **No dilution of this product is required.**
- **Use this potassium phosphates in sodium chloride injection product only in patients who require the entire 15 mmoL phosphorus dose (potassium 22 mEq) and not any fraction thereof.**
- **If a dose of potassium phosphate is required that does not equal 15 mmoL of Potassium phosphates in Sodium Chloride Injection, then an alternative formulation of potassium phosphates should be considered.**

- Visually inspect the solution for particulate matter and discoloration prior to administration. Do not administer unless solution is clear.
- Always inspect the solution container before and after removal from the pouch.
- Place the solution container on a clean, flat surface. Remove the solution container from the pouch.
- Check the solution container for leaks by squeezing firmly. Discard if leaks are found.
- Immediately before inserting the infusion set, remove twist-off port from the infusion bag.
- Use a non-vented infusion set or close the air-inlet on a vented set.
- Close the roller clamp of the infusion set.
- Hold the base of the infusion port, twist, and push spike until fully inserted. The infusion port contains a membrane that helps prevent leakage after removing the spike. The infusion port is not intended to be spiked more than once.
- Suspend solution container from hanger hole.
- For single-dose only. Discard unused portion.

2.2 Important Administration Instructions

- Check serum potassium and calcium concentrations prior to administration. Normalize the serum calcium level before administering Potassium Phosphates in Sodium Chloride Injection *[see Contraindications (4), Warnings and Precautions (5.3, 5.4)]*.

- Potassium Phosphates in Sodium Chloride Injection is only for administration to a patient with a serum potassium concentration less than 4 mEq/dL *[see Warnings and Precautions (5.3)]*. If the potassium concentration is 4 mEq/dL or more, use an alternative source of phosphorus.
- Use of this potassium phosphates in sodium chloride injection product increases the risk of hyperkalemia in adults and pediatric patients weighing less than 40 kg, including life threatening cardiac events *[see Warnings and Precautions (5.3)]*.
- Do not infuse with calcium-containing intravenous fluids *[see Warnings and Precautions (5.4)]*.
- The rate of administration may be dependent on the patient and the specific institution policy *[see Dosage and Administration (2.2)]*.
- When administered peripherally, a generally recommended maximum concentration is phosphorus 6.8 mmol/100 mL (potassium 10 mEq/100 mL).

2.3 Recommended Dosage

- This potassium phosphates in sodium chloride injection product contains phosphorus 15 mmol and potassium 22 mEq (phosphorus 0.06 mmol/mL and potassium 0.088 mEq/mL). Patients with body weight greater than 96 kg will receive a dose of less than 0.16 mmol/kg phosphorus.
- The phosphorus doses in Table 1 are general recommendations for an initial or single dose of potassium phosphates and are intended for most patients *[see Warnings and Precautions (5.1)]*.
- Consider overall volume status of the patient when determining whether Potassium Phosphates in Sodium chloride Injection is an appropriate product for phosphorus replacement.

- In patients with moderate renal impairment (eGFR ≥ 30 mL/min/1.73 m^2 to < 60 mL/min/1.73 m^2), start at the low end of the dose range *[see Use in Specific Populations (8.6)]*.
- Monitor serum phosphorus, potassium, calcium, and magnesium concentrations.

TABLE 1: Recommended Initial or Single Doses of Potassium Phosphates to Correct Hypophosphatemia in Adults and Pediatric Patients Weighing 40 kg or Greater

Serum Phosphorus Concentration[a]	**Phosphorus Dosage[b,c]**	**Corresponding Potassium Content**
1.8 mg/dL to lower end of the reference range[a]	0.16 mmol/kg to 0.31 mmol/kg	Potassium 0.23 mEq/kg to 0.46 mEq/kg
1 mg/dL to 1.7 mg/dL	0.32 mmol/kg to 0.43 mmol/kg	Potassium 0.47 mEq/kg to 0.63 mEq/kg
Less than 1 mg/dL	0.44 mmol/kg to 0.64 mmol/kg[c]	Potassium 0.64 mEq/kg to 0.94 mEq/kg

[a] Serum phosphorus reported using 2.5 mg/dL as the lower end of the reference range for healthy adults and pediatric patients 12 months of age and older. Serum phosphorus concentrations may vary depending on the assay used and the laboratory reference range.
[b] Weight is in terms of actual body weight. Limited information is available regarding dosing of patients significantly above ideal body weight; consider using an adjusted body

weight for these patients.
[c] This single-dose preparation of Potassium Phosphates in Sodium Chloride Injection contains phosphorus 15 mmol and potassium 22 mEq. Additional dose(s) following the initial dose may be needed in some patients.

Intravenous Infusion Rate

- The infusion rate is dependent upon whether administration will be through a peripheral or central venous catheter. The maximum recommended infusion rates are shown in Table 2 for adults and pediatric patients 12 years of age and older.

TABLE 2: Maximum Recommended Infusion Rate of Potassium Phosphates in Sodium Chloride Injection for Adults and Pediatric Patients Weighing 40 kg or Greater

Route of Administration	**Maximum Infusion Rate**
Peripheral Venous Catheter	phosphorus 6.8 mmol/hour (potassium 10 mEq/hour)
Central Venous Catheter	phosphorus 15 mmol/hour (potassium 22 mEq/hour)

Continuous electrocardiographic (ECG) monitoring and infusion through a central venous catheter is recommended for infusion rates higher than potassium 10 mEq/hour.

Repeated Dosing

Additional dose(s) following the initial dose may be needed in some patients. Prior to administration of additional doses, assess the patient clinically, obtain serum phosphorus, calcium, and potassium concentrations and adjust the dose accordingly.

3 DOSAGE FORMS AND STRENGTHS

Potassium Phosphates in 0.9% Sodium Chloride Injection is a clear, colorless solution filled in a single-dose intravenous infusion bag and supplied as:

- Phosphorus 15 mmol/250 mL (0.06 mmol/mL) and Potassium 22 mEq/250 mL (0.088 mEq/mL)

4 CONTRAINDICATIONS

Potassium Phosphates in Sodium Chloride Injection is contraindicated in patients with:

- hyperkalemia *[see Warnings and Precautions (5.3)]*
- hyperphosphatemia *[see Warnings and Precautions (5.4)]*
- hypercalcemia or significant hypocalcemia *[see Warnings and Precautions (5.4)]*
- severe renal impairment (eGFR less than 30 mL/min/1.73m^2) or end stage renal disease *[see Warnings and Precautions (5.3)]*

5 WARNINGS AND PRECAUTIONS

5.1 Serious Cardiac Adverse Reactions with Rapid Intravenous Administration

Intravenous administration of potassium phosphates to correct hypophosphatemia in single-doses of phosphorus 50 mmol and greater and/or at rapid infusion rates (over 1 to 3 hours) has resulted in death, cardiac arrest, cardiac arrhythmia (including QT prolongation), hyperkalemia, hyperphosphatemia and seizures *[see Overdosage (10)].*

Potassium Phosphates in Sodium Chloride Injection is for *intravenous infusion*. No dilution of this product is required. The maximum initial or single-dose of potassium phosphates 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. 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 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 in Sodium Chloride Injection may increase the risk of hyperkalemia, including life-threatening cardiac events, especially when administered in excessive doses 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 in Sodium Chloride Injection and do not exceed the maximum age-appropriate recommended daily amount of potassium. In patients with moderate renal impairment (eGFR $\geq$ 30 mL/min/1.73 m^2 to $<$ 60 mL/min/1.73 m^2), start at the low end of the dose range and monitor serum potassium, phosphorus, calcium, and magnesium concentrations *[see Dosage and Administration (2.2), Use in Specific Populations (8.6)]*.

When administering Potassium Phosphates in Sodium Chloride Injection 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 in Sodium Chloride Injection and use an alternative source of phosphorus *[see Dosage and Administration (2.1)]*.

The maximum initial or single-dose of potassium phosphates 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 in Sodium Chloride Injection. Potassium Phosphates in Sodium Chloride Injection is contraindicated in patients with hyperphosphatemia and/or hypercalcemia *[see Contraindications (4)].*

Monitor serum phosphorus and calcium concentrations during treatment with Potassium Phosphates in Sodium Chloride Injection *[see Dosage and Administration (2.2)]*.

5.5 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.

5.6 Vein Damage and Thrombosis

The infusion of potassium phosphates 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.

5.7 Laboratory Monitoring

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

6 ADVERSE REACTIONS

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

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

The following adverse reactions in Table 3 have been reported in clinical studies or post-marketing 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 3: Adverse Reactions Reported in Clinical Studies or Post-marketing Reports with Intravenous Potassium Phosphates

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

7 DRUG INTERACTIONS

7.1 Other Products that Increase Serum Potassium

Administration of Potassium Phosphates in Sodium Chloride 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 in Sodium Chloride Injection in patients receiving such products. If use cannot be avoided, closely monitor serum potassium concentrations *[see Dosage and Administration (2.2)]*.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Administration of the recommended dose of Potassium Phosphates in Sodium Chloride Injection is not expected to cause major birth defects, miscarriage, or adverse maternal or fetal outcomes. Consider potassium phosphate replacement if correction of hypophosphatemia via the enteral route is not possible *(see Clinical Considerations).* Animal reproduction studies have not been conducted with Potassium Phosphates in Sodium Chloride Injection.

The 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. Intravenous replacement with potassium phosphate should be considered if a pregnant woman requires intravenous replacement to correct hypophosphatemia when the enteral route is not possible, insufficient or contraindicated.

8.2 Lactation

Risk Summary

Phosphorus and potassium are present in human milk. Administration of the recommended dose of Potassium Phosphates in Sodium Chloride Injection is not expected to cause harm to a breast-fed 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 in Sodium Chloride Injection and any potential adverse effects on the breastfed child from Potassium Phosphates in Sodium Chloride Injection or from underlying maternal condition.

8.4 Pediatric Use

Safety and effectiveness of Potassium Phosphates in Sodium Chloride Injection have been established in pediatric patients weighing 40 kg or more as a source of phosphorus to correct hypophosphatemia when oral or enteral replacement is not possible, insufficient, or contraindicated. However, this potassium phosphates in sodium chloride injection product is not approved for use in pediatric patients who weigh less than 40 kg because of the lack of an appropriate formulation.

8.5 Geriatric Use

In general, dose selection of Potassium Phosphates in Sodium Chloride 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 in Sodium Chloride Injection may be greater in patients with impaired renal function *[see Warnings and Precautions (5.3, 5.4)]*.

Potassium Phosphates in Sodium Chloride Injection is contraindicated due to the risk of hyperkalemia in patients with severe renal impairment (eGFR less than 30 mL/min/1.73 m^2) or end stage renal disease *[see Contraindications (4)]*.

In patients with moderate renal impairment (eGFR ≥ 30 mL/min/1.73 m^2 to < 60 mL/min/1.73 m^2), start at the low end of the dosage range and monitor serum potassium, phosphorus, calcium, and magnesium concentrations *[see Dosage and Administration (2.2)].*

10 OVERDOSAGE

Hyperphosphatemia

Administration of excessive doses of intravenous potassium phosphates 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 in 0.9% Sodium Chloride Injection, for intravenous use, is a phosphorus replacement product containing phosphorus 0.06 mmol/mL and potassium 0.088 mEq/mL. It is a sterile, non-pyrogenic, ready-to-use diluted solution containing a mixture of monobasic potassium phosphate, USP and dibasic potassium phosphate, USP in 0.9% sodium chloride. No dilution is required before administration. It is supplied in 250 mL single-dose intravenous infusion bag.

Monobasic Potassium Phosphate is chemically designated KH_2PO_4, molecular weight 136.09, white, odorless crystals or granules freely soluble in water.

Dibasic Potassium Phosphate is chemically designated K_2HPO_4, molecular weight 174.18, colorless or white granular salt freely soluble in water.

Each mL contains 4.48 mg of monobasic potassium phosphate, USP and 4.72 mg of dibasic potassium phosphate, USP.

Each mL contains phosphorus, 0.06 mmol (equivalent to 1.86 mg phosphorus); potassium, 0.088 mEq (equivalent to 3.40 mg of potassium); sodium chloride, USP, 9 mg and water for injection, USP (q.s.).

Note: 1 mmol of phosphorus is equal to 1 mmol phosphate.

This product contains no more than 25 mcg/L of aluminum.

The pH is 5.8 to 7.2 and the osmolarity is 0.455 mOsmol/mL (calc).

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.

12.2 Pharmacodynamics

The exposure-response relationship and time course of pharmacodynamic response for the safety and effectiveness of potassium phosphates have not been fully characterized.

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 in 0.9% Sodium Chloride Injection is a clear, colorless solution filled in an intravenous infusion bag containing phosphorus 15 mmol/250 mL (0.06 mmol/mL) and potassium 22mEq/250mL (0.088 mEq/mL). It is supplied as:

One 250 mL Single-dose Infusion Bag in a Pouch: NDC 70121-1722-1

24 Pouches in a Shipper (Unit of sale): NDC 70121-1722-9

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature]. Keep covered in a pouch until time of use.

Each ready-to-use infusion bag contains no preservatives. Once the ready-to-use infusion bag has been removed from the pouch, the ready-to-use infusion bag should be used within 24 hours, with any unused portion discarded.

17 PATIENT COUNSELING INFORMATION

Inform patients, caregivers, or home healthcare providers of the following risks of Potassium Phosphates in Sodium Chloride Injection:

- Advise patients of the serious cardiac risks (e.g., death, cardiac arrest, cardiac arrhythmia, hyperkalemia, hyperphosphatemia, and seizures) associated with rapid administration of Potassium Phosphate in Sodium Chloride Injection *[see Warnings and Precautions (5.1)].*
- Advise patients that Potassium Phosphate in Sodium Chloride Injection may increase the risk of hyperkalemia when administered in excessive doses or by rapid intravenous infusion *[see Warnings and Precautions (5.3)].*
- Advise patients that hyperphosphatemia can occur, especially in patients with renal impairment, which can result in hypocalcemia *[see Warnings and Precautions (5.4)].*
- Advise patients that Potassium Phosphate in Sodium Chloride Injection has been reported to cause hypomagnesemia when administered to patients with hypercalcemia and diabetic ketoacidosis *[see Warnings and Precautions (5.5)].*

For additional information go to www.amneal.com or call 1-877-835-5472.

Manufactured by:

Amneal Pharmaceuticals Pvt. Ltd.

Mehsana 382165, INDIA

Distributed by:

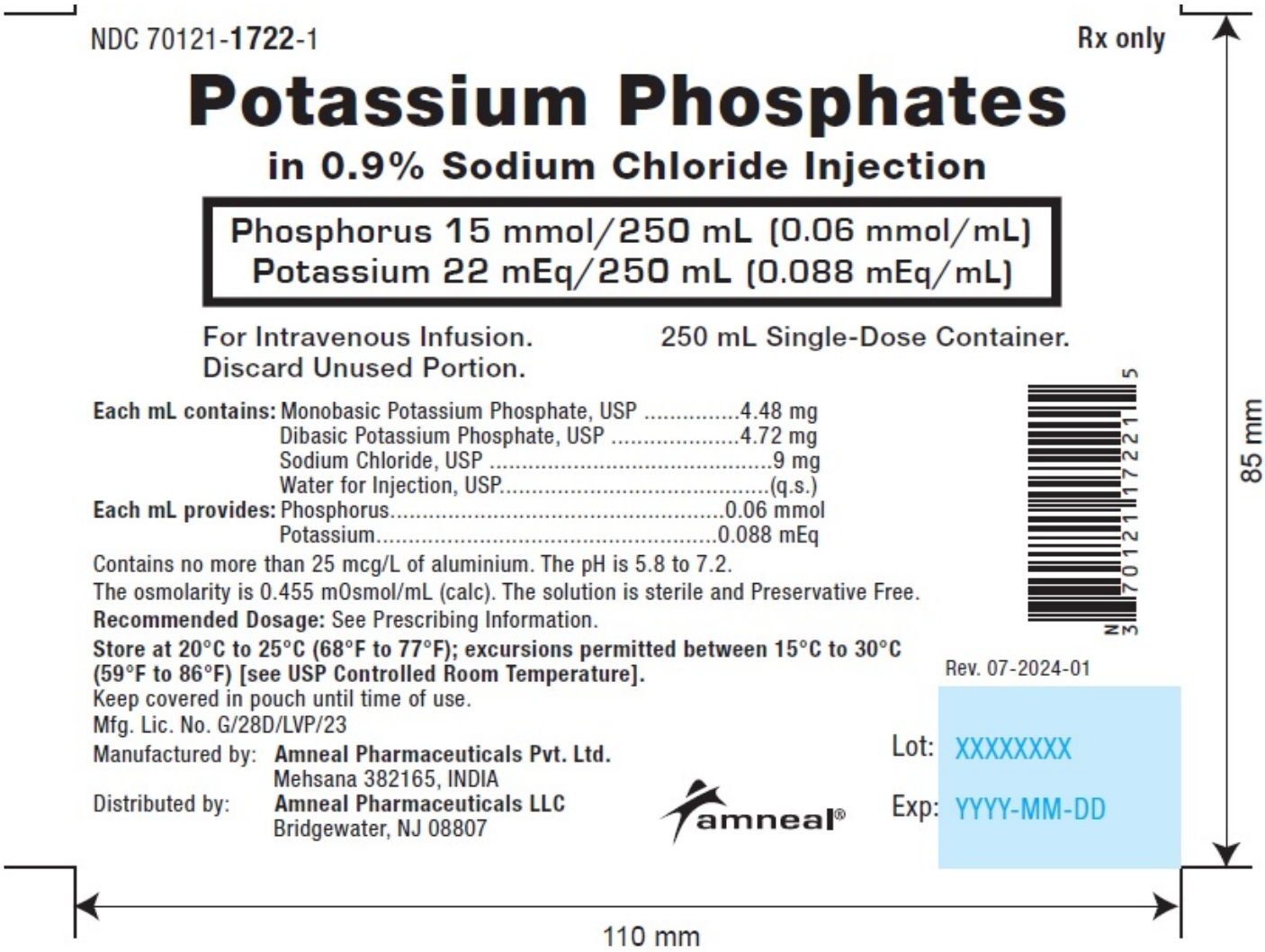
Amneal Pharmaceuticals LLC

Bridgewater, NJ 08807

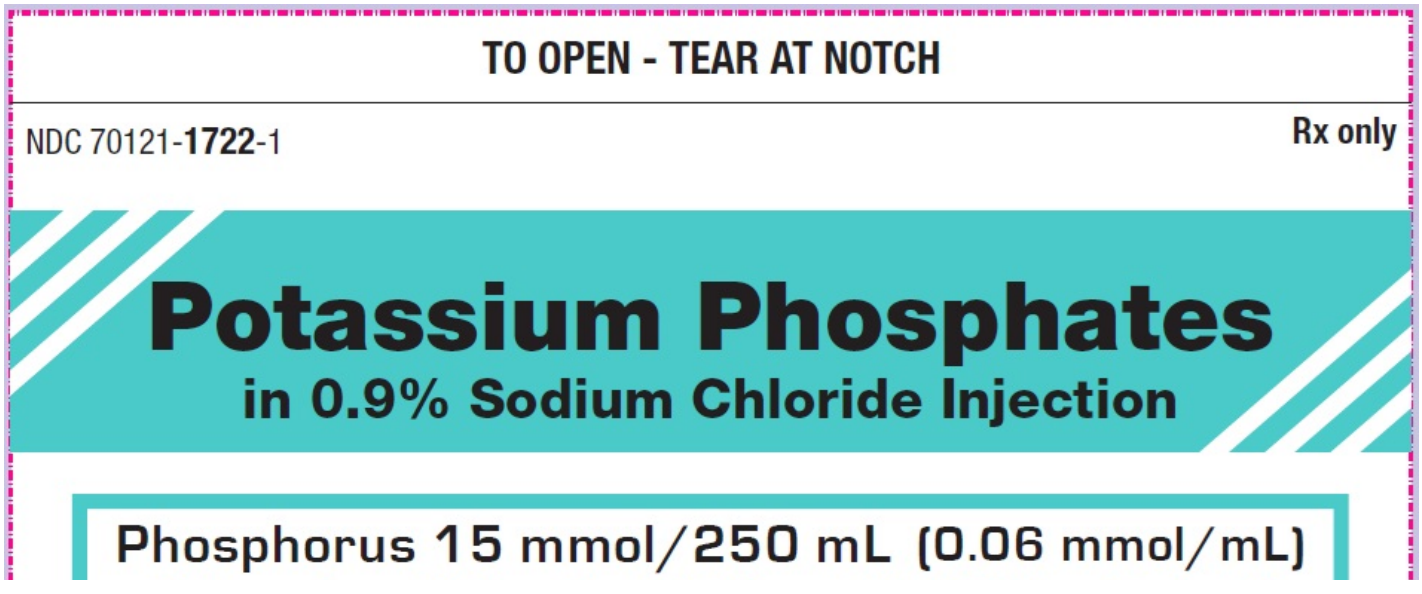
Rev. 07-2024-01

PRINCIPAL DISPLAY PANEL

NDC 70121-1722-1
Potassium Phosphates in 0.9% Sodium Chloride Injection
Phosphorus 15 mmol/250 mL (0.06 mmol/ mL)
Potassium 22 mEq/250 mL (0.088 mEq/mL)
Intravenous Bag Label
Rx only
Amneal Pharmaceuticals LLC



NDC 70121-1722-1
Potassium Phosphates in 0.9% Sodium Chloride Injection
Phosphorus 15 mmol/250 mL (0.06 mmol/ mL)
Potassium 22 mEq/250 mL (0.088 mEq/mL)
Pouch Label
Rx only
Amneal Pharmaceuticals LLC



Potassium 22 mEq/250 mL (0.088 mEq/mL)

For Intravenous Infusion. 250 mL Single-Dose Container.
Discard Unused Portion.

Each mL contains: Monobasic Potassium Phosphate, USP.....4.48 mg
Dibasic Potassium Phosphate, USP.....4.72 mg
Sodium Chloride, USP.....9 mg
Water for Injection, USP.....(q.s.)

Each mL provides: Phosphorus.....0.06 mmol
Potassium.....0.088 mEq

Contains no more than 25 mcg/L of aluminium. The pH is 5.8 to 7.2.

The osmolarity is 0.455 mOsmol/mL (calc).
The solution is Sterile and Preservative Free.

Recommended Dosage: See Prescribing Information.

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

Keep covered in pouch until time of use.

Once the ready-to-use infusion bag has been removed from the pouch, the ready-to-use infusion bag should be used within 24 hours, with any unused portion discarded.

Visually inspect the solution for particulate matter and discoloration prior to administration.

Do not use if the solution is colored or cloudy, or if it contains particulate matter.

N 3 70121 17221 5

LOT : XXXXXXXX
EXP : YYYY-MM-DD

Manufactured by:
Amneal Pharmaceuticals Pvt. Ltd.
Mehsana 382165, INDIA

Distributed by:
Amneal Pharmaceuticals LLC
Bridgewater, NJ 08807

Mfg. Lic. No. G/28D/LVP/23 Rev. 07-2024-01

amneal®

NDC 70121-1722-9
Potassium Phosphates in 0.9% Sodium Chloride Injection
Phosphorus 15 mmol/250 mL (0.06 mmol/ mL)
Potassium 22 mEq/250 mL (0.088 mEq/mL)
Carton Label
Rx only
Amneal Pharmaceuticals LLC

NDC 70121-**1722**-9

24 x 250 mL Single-Dose Containers

Potassium Phosphates

in 0.9% Sodium Chloride Injection

Phosphorus 15 mmol/250 mL (0.06 mmol/mL)
Potassium 22 mEq/250 mL (0.088 mEq/mL)

For Intravenous Infusion. Discard Unused Portion.

Each mL contains:
Monobasic Potassium Phosphate, USP.....4.48 mg
Dibasic Potassium Phosphate, USP.....4.72 mg
Sodium Chloride, USP.....9 mg
Water for Injection, USP.....(q.s.)

Each mL provides:
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Potassium.....0.088 mEq

Contains no more than 25 mcg/L of aluminium. The pH is 5.8 to 7.2.
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Keep covered in pouch until time of use.

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Distributed by: **Amneal Pharmaceuticals LLC**
Bridgewater, NJ 08807

Mfg. Lic. No. G/28D/LVP/23

Rx only

amneal®

Rev. 07-2024-01

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GTIN : XXXXXXXXXXXXXX
SR. NO. : XXXXXXXXXX
EXP : YYYY-MM-DD
LOT : XXXXXXX

POTASSIUM PHOSPHATES

potassium phosphates in sodium chloride injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70121-1722
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51) (POTASSIUM CATION - UNII:295O53K152, PHOSPHATE ION - UNII:NK08V8K8HR)	POTASSIUM PHOSPHATE, MONOBASIC	4.48 mg in 1 mL
POTASSIUM PHOSPHATE, DIBASIC (UNII: CI71S98N1Z) (POTASSIUM CATION - UNII:295O53K152, PHOSPHATE ION - UNII:NK08V8K8HR)	POTASSIUM PHOSPHATE, DIBASIC	4.72 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	9 mg in 1 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70121-1722-9	24 in 1 CARTON	07/30/2024	
1		1 in 1 POUCH		
1		250 mL in 1 BAG; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA218343	07/30/2024	

Labeler - Amneal Pharmaceuticals LLC (827748190)

Establishment

Name	Address	ID/FEI	Business Operations
Amneal Pharmaceuticals Private Limited		854377396	analysis(70121-1722) , label(70121-1722) , manufacture(70121-1722) , pack(70121-1722) , sterilize(70121-1722)

Revised: 7/2024 Amneal Pharmaceuticals LLC