

## POTASSIUM CHLORIDE- potassium chloride injection, solution

Nexus Pharmaceuticals, Inc.

### POTASSIUM CHLORIDE INJECTION

For Use Only With A Calibrated Infusion Device

#### Highly Concentrated

Flexible Plastic Container

Ready To Use

Rx only

#### DESCRIPTION

This Potassium Chloride Injection is a sterile, nonpyrogenic, highly concentrated, ready-to-use solution of Potassium Chloride, USP in Water for Injection, USP for electrolyte replenishment in a single dose container for intravenous administration. It contains no antimicrobial agents.

Potassium Chloride Injection mEq Potassium/ Container	Composition (g/L) Potassium Chloride, USP (KCl)	Osmolarity* (mOsmol/L) (calc)	pH	Ionic Concentration (mEq/L)	
				Potassium	Chloride
10 mEq/100 mL	7.45	<b>200</b>	5.8 (4.0 to 8.0)	<b>100</b>	100
10 mEq/50 mL 20 mEq/100 mL	14.9	<b>400</b>	5.8 (4.0 to 8.0)	<b>200</b>	200
20 mEq/50 mL 40 mEq/100 mL	29.8	<b>799</b>	5.8 (4.0 to 8.0)	<b>400</b>	400

\*Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L. Administration of substantially hypertonic solutions ( $\geq 600$  mOsmol/L) may cause vein damage.

#### CLINICAL PHARMACOLOGY

Potassium is the major cation of body cells (160 mEq/liter of intracellular water) and is concerned with the maintenance of body fluid composition and electrolyte balance. Potassium participates in carbohydrate utilization, protein synthesis, and is critical in the regulation of nerve conduction and muscle contraction, particularly in the heart. Chloride, the major extracellular anion, closely follows the metabolism of sodium, and changes in the acid-base of the body are reflected by changes in the chloride concentration.

Normally about 80 to 90% of the potassium intake is excreted in the urine, the remainder in the stools and to a small extent, in the perspiration. The kidney does not conserve potassium well so that during fasting, or in patients on a potassium-free diet, potassium loss from the body continues resulting in potassium depletion. A deficiency of either potassium or chloride will lead to a deficit of the other.

#### INDICATIONS AND USAGE

Potassium Chloride Injection is indicated in the treatment of potassium deficiency states when oral replacement is not feasible.

**THIS HIGHLY CONCENTRATED, READY-TO-USE POTASSIUM CHLORIDE INJECTION IS INTENDED FOR THE MAINTENANCE OF SERUM K<sup>+</sup> LEVELS AND FOR POTASSIUM SUPPLEMENTATION IN FLUID RESTRICTED PATIENTS WHO CANNOT ACCOMMODATE ADDITIONAL VOLUMES OF FLUID ASSOCIATED WITH POTASSIUM SOLUTIONS OF LOWER CONCENTRATION.**

When using these products, these patients should be on continuous cardiac monitoring and frequent testing for serum potassium concentration and acid-base balance.

#### CONTRAINDICATIONS

Potassium Chloride Injection is contraindicated in diseases where high potassium levels may be encountered, and in patients with hyperkalemia, renal failure and in conditions in which potassium retention is present.

#### WARNINGS

**THIS HIGHLY CONCENTRATED, READY-TO-USE POTASSIUM CHLORIDE INJECTION IS INTENDED FOR THE MAINTENANCE OF SERUM K<sup>+</sup> LEVELS AND FOR POTASSIUM SUPPLEMENTATION IN FLUID RESTRICTED PATIENTS WHO CANNOT ACCOMMODATE ADDITIONAL VOLUMES OF FLUID ASSOCIATED WITH POTASSIUM SOLUTIONS OF LOWER CONCENTRATION.**

**TO AVOID POTASSIUM INTOXICATION, DO NOT INFUSE THESE SOLUTIONS RAPIDLY.**

**PATIENTS REQUIRING HIGHLY CONCENTRATED SOLUTIONS SHOULD BE KEPT ON CONTINUOUS CARDIAC MONITORING AND UNDERGO FREQUENT TESTING FOR SERUM POTASSIUM AND ACID-BASE BALANCE, ESPECIALLY IF THEY RECEIVE DIGITALIS.**

In patients with renal insufficiency, administration of potassium chloride may cause potassium intoxication and life-threatening hyperkalemia.

**Administer intravenously only with a calibrated infusion device at a slow, controlled rate. (See *DOSAGE AND ADMINISTRATION*.) Because pain associated with peripheral infusion of Potassium Chloride solution has been reported, whenever possible administration via a central route is recommended for thorough dilution by the blood stream and avoidance of extravasation. The highest concentration (400 mEq/L) should be exclusively administered via central route.**

The administration of intravenous solutions can cause fluid and/or solute overload resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentration. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentration.

#### PRECAUTIONS

##### Laboratory Tests

Serum potassium levels are not necessarily indicative of tissue potassium levels. Solutions containing potassium should be used with caution in the presence of cardiac or renal disease.

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid-base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation. Significant deviations from normal concentrations may require the use of additional electrolyte supplements, or the use of electrolyte-free dextrose solutions to which individualized electrolyte supplements may be added.

##### Pregnancy:

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

##### Pediatric Use:

These products should not be used in pediatric patients at this time.

Do not administer unless solution is clear and seal is intact.

#### ADVERSE REACTIONS

Potassium intoxication with mild or severe hyperkalemia has been reported. The signs and symptoms of intoxication include paresthesia of the extremities, areflexia, muscular or respiratory paralysis, mental confusion, weakness, hypotension, cardiac arrhythmia, heart block, electrographic abnormalities and cardiac arrest. EKG abnormalities serve as a clinical reflection of the seriousness of changes in serum potassium concentrations: peaked T waves and prolonged P-R intervals usually occur with modest elevations above the upper limit of normal potassium concentrations; P waves disappear, the QRS complex widens, and eventual asystole usually occurs with higher elevations.

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

Infusion of highly concentrated potassium chloride solutions may cause local pain and vein irritation. (See **WARNINGS**).

Reactions reported with the use of potassium-containing solutions include nausea, vomiting, and abdominal pain and diarrhea.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

### OVERDOSAGE

In the event of hyperkalemia, discontinue the infusion immediately and institute corrective therapy to reduce serum potassium levels as necessary. The use of potassium containing foods or medications must also be eliminated.

Treatment of mild to severe hyperkalemia with signs and symptoms of potassium intoxication includes the following:

1. Dextrose Injection, USP, 10% or 25%, containing 10 units of crystalline insulin per 20 grams of dextrose administered intravenously, 300 to 500 mL per hour.
2. Absorption and exchange of potassium using sodium or ammonium cycle cation exchange resin, orally and as retention enema.
3. Hemodialysis and peritoneal dialysis.

In cases of digitalization, too rapid a lowering of plasma potassium concentration can cause digitalis toxicity.

### DOSAGE AND ADMINISTRATION

The dose and rate of administration are dependent upon the specific condition of each patient.

**Administer intravenously only with a calibrated infusion device at a slow, controlled rate. Because pain associated with peripheral infusion of Potassium Chloride solution has been reported, whenever possible, administration via central route is recommended for thorough dilution by the blood stream and avoidance of extravasation. The Highest concentration (400 mEq/L) should be exclusively administered via central route.**

Recommended administration rates should not usually exceed 10 mEq/hour or 200 mEq for a 24-hour period if the serum potassium level is greater than 2.5 mEq/liter.

In urgent cases where the serum potassium level is less than 2 mEq/liter or where severe hypokalemia is a threat (serum potassium level less than 2 mEq/liter and electrocardiographic changes and/or muscle paralysis), rates up to 40 mEq/hour or 400 mEq over a 24-hour period can be administered very carefully when guided by continuous monitoring of the EKG and frequent serum K<sup>+</sup> determinations to avoid hyperkalemia and cardiac arrest.

Parenteral drug products should be inspected visually for particulate matter and discoloration, whenever solution and container permit. Use of a final filter is recommended during administration of all parenteral solutions where possible.

Do not add supplementary medication.

### Preparation for Administration

#### (Use aseptic technique)

1. Close flow control clamp of administration set.
2. Remove cover from outlet port at bottom of container.
3. Insert piercing pin of administration set into port with a twisting motion until the set is firmly seated.

**NOTE:** See full directions on administration set carton.

4. Suspend container from hanger.

5. Squeeze and release drip chamber to establish proper fluid level in chamber.
6. Open flow control clamp and clear air from set. Close clamp.
7. Attach set to venipuncture device. If device is not indwelling, prime and make venipuncture.
8. Regulate rate of administration with flow control clamp.

**WARNING:** Do not use flexible container in series connections. Do not add supplementary medication. Such use could result in air embolism due to residual air being drawn from the primary container before administration of the fluid from the secondary container is completed.

### HOW SUPPLIED

Potassium Chloride Injection in flexible plastic containers is available as follows:

NDC for each individual IV Bag	Potassium per container
14789-109-16	10 mEq/100 mL
14789-108-08	10 mEq/50 mL
14789-108-16	20 mEq/100 mL
14789-107-08	20 mEq/50 mL
14789-107-16	40 mEq/100 mL

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

Manufactured in the UK

Manufactured for Nexus Pharmaceuticals, Inc.,  
Lincolnshire, IL 60069 USA

KCLPIR001

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