**POTASSIUM CHLORIDE- potassium chloride injection**
**Nexus Pharamaceuticals Inc.**

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**Rx only**

**Potassium Chloride**
for Injection
**Concentrate**, USP

| **CONCENTRATE** |
|---|
| *MUST BE DILUTED BEFORE USE.* |

***FOR INTRAVENOUS INFUSION ONLY; MUST BE DILUTED PRIOR TO INJECTION***.

**Fliptop Vials**

## DESCRIPTION

Potassium Chloride for Injection Concentrate, USP, is a sterile, nonpyrogenic, concentrated solution of potassium chloride, USP in water for injection administered by intravenous infusion only after dilution in a larger volume of fluid. They are provided in the following variety of concentrations and sizes comprising a choice of single-dose containers, all designed to provide the commonly prescribed amounts of potassium chloride for single-dose infusion after dilution in suitable large volume parenterals.

| **Additive Solution* (conc. & size)** | **K+ mEq/mL** | **KCl mg/mL** | **mOsmol/mL (calc.)** |
|---|---|---|---|
| 20 mEq/10 mL | 2 | 149 | 4 |
| 40 mEq/20 mL | 2 | 149 | 4 |

* May contain hydrochloric acid for pH adjustment.

The solutions contain no bacteriostat, antimicrobial agent or added buffer (except for pH adjustment) and each is intended only for single-dose injection (after dilution). When smaller doses are required, discard the unused portion. The pH is 4.6 (4.0 to 8.0).

Potassium Chloride for Injection Concentrate, USP (appropriately diluted) is a parenteral fluid and electrolyte replenisher.

Potassium Chloride, USP is chemically designated KCl, a white granular powder freely soluble in water.

## CLINICAL PHARMACOLOGY

Potassium is the chief 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 and 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 balance 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 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 for Injection Concentrate, USP is indicated in the treatment of potassium deficiency states when oral replacement is not feasible.

## CONTRAINDICATIONS

Potassium Chloride for Injection Concentrate, USP 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

### Potentially Fatal Cardiac Adverse Reactions with Undiluted Intravenous Administration

Direct patient injection of potassium chloride at this concentration may be instantaneously fatal. Potassium Chloride for Injection Concentrate must be diluted before administration. Fatal cardiac arrhythmia and cardiac arrest have occurred when potassium chloride was administered in an undiluted form.

To avoid potassium intoxication, do not infuse these solutions rapidly. In patients with renal insufficiency, administration of potassium chloride may cause potassium intoxication and life-threatening hyperkalemia.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. 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

### General

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.

Potassium therapy should be guided primarily by serial electrocardiograms, especially in patients receiving digitalis. Serum potassium levels are not necessarily indicative of tissue potassium levels. Solutions containing potassium should be used with caution in the presence of cardiac disease, particularly in the presence of renal disease, and in such instances, cardiac monitoring is recommended.

Solutions containing dextrose should be used with caution in patients with overt or known subclinical diabetes mellitus, or carbohydrate intolerance for any reason.

If the administration is controlled by a pumping device, care must be taken to discontinue pumping action before the container runs dry or air embolism may result.

### Pregnancy

*Teratogenic Effects*: 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.

## ADVERSE REACTIONS

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, hypervolemia, and hyperkalemia.

Too rapid infusion of hypertonic solutions may cause local pain and, rarely, vein irritation. Rate of administration should be adjusted according to tolerance.

Reactions reported with the use of potassium-containing solutions include nausea, vomiting, abdominal pain and diarrhea. The signs and symptoms of potassium intoxication include paresthesias of the extremities, areflexia, muscular or respiratory paralysis, mental confusion, weakness, hypotension, cardiac arrhythmias, heart block, electrocardiographic abnormalities and cardiac arrest. Potassium deficits result in disruption of neuromuscular function, and intestinal ileus and dilatation.

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.

**To report SUSPECTED ADVERSE REACTIONS, contact Lambda Therapeutics Limited at 1-855-642-2594 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch**.

## OVERDOSAGE

In the event of fluid overload during parenteral therapy, re-evaluate the patient's condition, and institute appropriate corrective treatment.

In the event of overdosage with potassium-containing solutions, discontinue the infusion immediately, and institute corrective therapy to reduce serum potassium levels.

Treatment of hyperkalemia includes the following:

1. Dextrose Injection USP, 10% or 25%, containing 10 units of crystalline insulin per 20 grams of dextrose administered intravenously, at a rate of 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. The use of potassium-containing foods or medications must be eliminated. However, in cases of digitalization, too rapid a lowering of plasma potassium concentration can cause digitalis toxicity.

## DOSAGE AND ADMINISTRATION

Potassium Chloride for Injection Concentrate, USP must be diluted before administration. Care must be taken to ensure there is complete mixing of the potassium chloride with the large volume fluid, particularly if soft or bag type containers are used.

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

If the serum potassium level is greater than 2.5 mEq/liter, potassium can be given at a rate not to exceed 10 mEq/hour in a concentration of up to 40 mEq/liter. The 24-hour total dose should not exceed 200 mEq.

If urgent treatment is indicated (serum potassium level less than 2.0 mEq/liter with electrocardiographic changes and/or muscle paralysis) potassium chloride may be infused very cautiously at a rate of up to 40 mEq/hour. In such cases, continuous cardiac monitoring is essential. As much as 400 mEq may be administered in a 24 hour period. In critical conditions, potassium chloride may be administered in saline (unless contraindicated), rather than in dextrose containing fluids, as dextrose may lower serum potassium levels.

Prior to entering vial, remove the metal seal and cleanse the rubber closure with a suitable antiseptic agent.

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

TO PREVENT NEEDLE-STICK INJURIES, NEEDLES SHOULD NOT BE RECAPPED, PURPOSELY BENT, OR BROKEN BY HAND.

## HOW SUPPLIED

Potassium Chloride for Injection Concentrate, USP, is supplied in single-dose containers as follows:

| Unit of Sale | Concentration |
|---|---|
| **NDC 14789-136-05**<br>Tray of 25 single-dose containers | 20 mEq/10 mL<br>(2 mEq/mL) |
| **NDC 14789-137-05**<br>Tray of 25 single-dose containers | 40 mEq/20 mL<br>(2 mEq/mL) |

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

Container closure was not made with natural rubber latex.

Manufactured in the USA by:
Nexus Pharmaceuticals, Inc.
Lincolnshire

KCVPI01R02
Revised: 3/2023

**Principal Display Panel – 10 mL Carton Label**

NDC 14789-**136**-05

Rx only

**Potassium Chloride**

For Injection **Concentrate**, USP

**20 mEq/10mL** (2 mEq/mL)

**CONCENTRATE**

*MUST BE DILUTED BEFORE USE*

For Intravenous Use

25 x 10 mL
Single-dose Vials

NEXUS
PHARMACEUTICALS

NDC 14789-**136**-05

Rx only

# Potassium Chloride

For Injection **Concentrate**, USP

**20 mEq/10mL** (2 mEq/mL)

**CONCENTRATE**

*MUST BE DILUTED BEFORE USE*

For Intravenous Use

25 x 10 mL
Single-dose Vials

NEXUS PHARMACEUTICALS

Each mL contains potassium chloride, 2 mEq (149 mg).

May contain HCl for pH adjustment.

4 mOsmol/mL (calc). pH 4.6 ( 4.0 to 8.0). Sterile, nonpyrogenic.

For Intravenous Use only.

Usual dosage: See insert

Mix thoroughly after dilution. Use only if clear and seal is intact. Contains no bacteriostat, use promptly; discard unused portion.

Contains no more than 100 mcg/L of aluminum.

Container closure was not made with natural rubber latex.

NEXUS PHARMACEUTICALS

**USE ASEPTIC TECHNIQUE**

Remove cover from fliptop vial and cleanse stopper with antiseptic.
Add to a suitable solution in an intravenous container.
Mix throughly after dilution.

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

NEXUS PHARMACEUTICALS

Manufactured in the USA by:
Nexus Pharmaceuticals, Inc.
Lincolnshire, IL 60069, USA

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KCVCT01R01

**Principal Display Panel – 10 mL Vial Label**

NDC 14789-**136**-07

Rx only

**Potassium Chloride**

For Injection **Concentrate**, USP

**20 mEq/10mL** (2 mEq/mL)

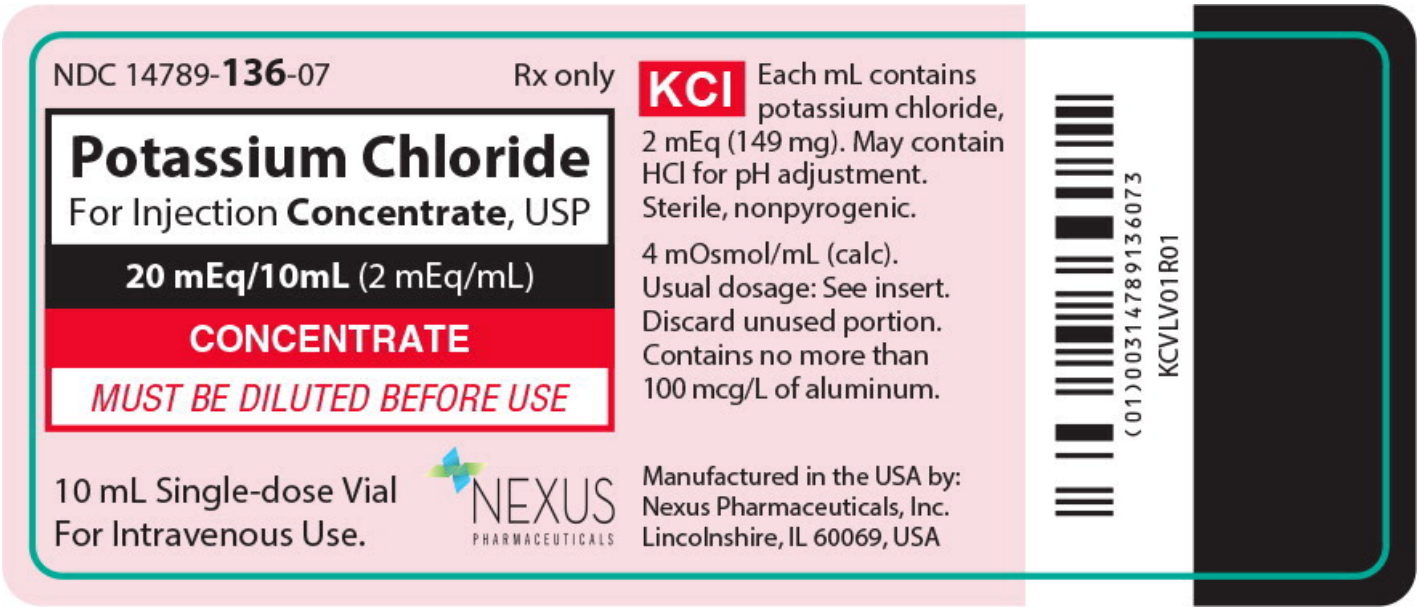
**CONCENTRATE**

*MUST BE DILUTED BEFORE USE*

10 mL Single-dose Vial

For Intravenous Use.

NEXUS
PHARMACEUTICALS




**Principal Display Panel – 20 mL Carton Label**

NDC 14789-**137**-05

Rx only

**Potassium Chloride**

For Injection **Concentrate**, USP

**40 mEq/20mL** (2 mEq/mL)

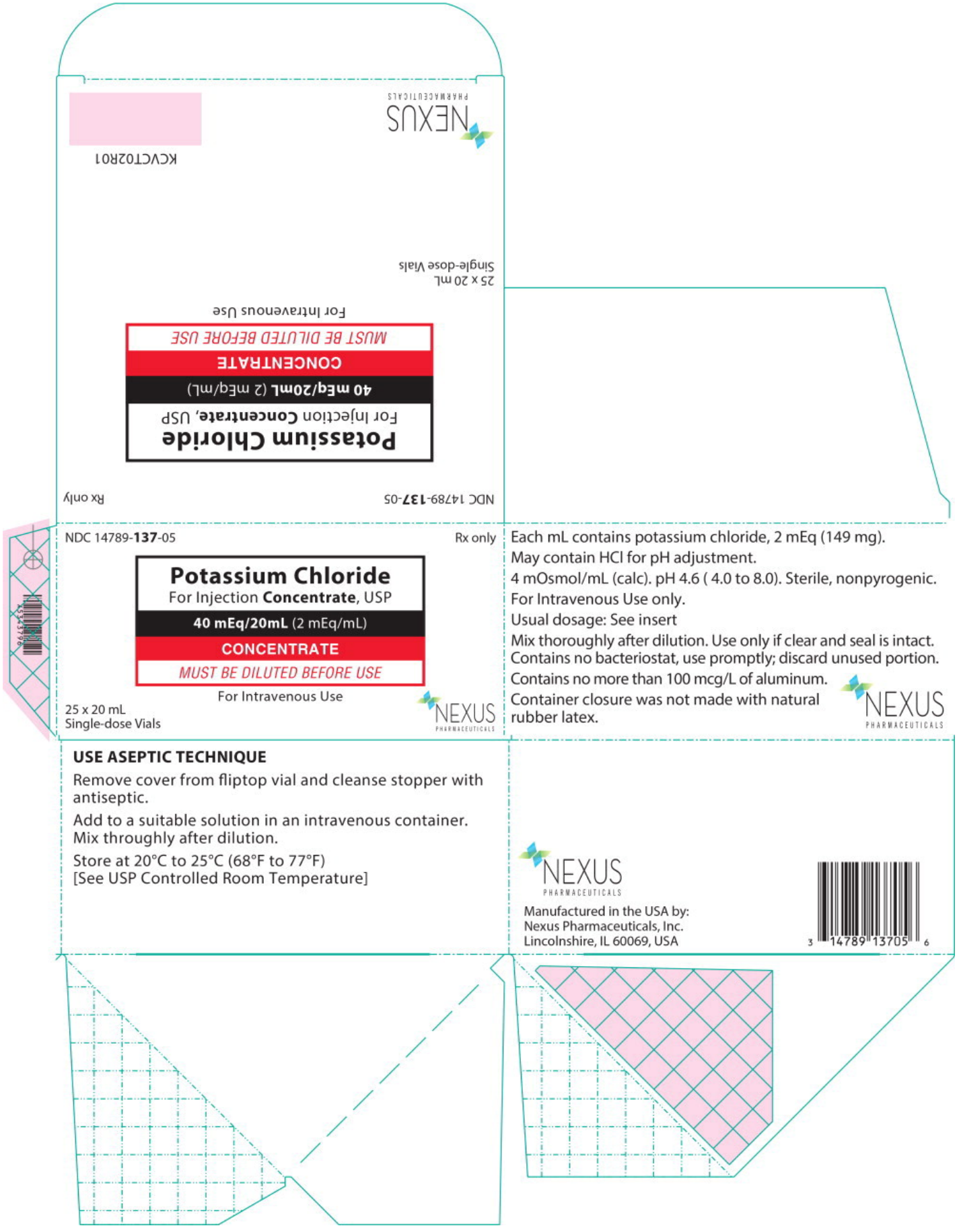
**CONCENTRATE**

*MUST BE DILUTED BEFORE USE*

For Intravenous Use

25 x 20 mL
Single-dose Vials

NEXUS
PHARMACEUTICALS




**Principal Display Panel – 20 mL Vial Label**

NDC 14789-**137**-07

Rx only

**Potassium Chloride**

For Injection **Concentrate**, USP

**40 mEq/20 mL**(2 mEq/mL)

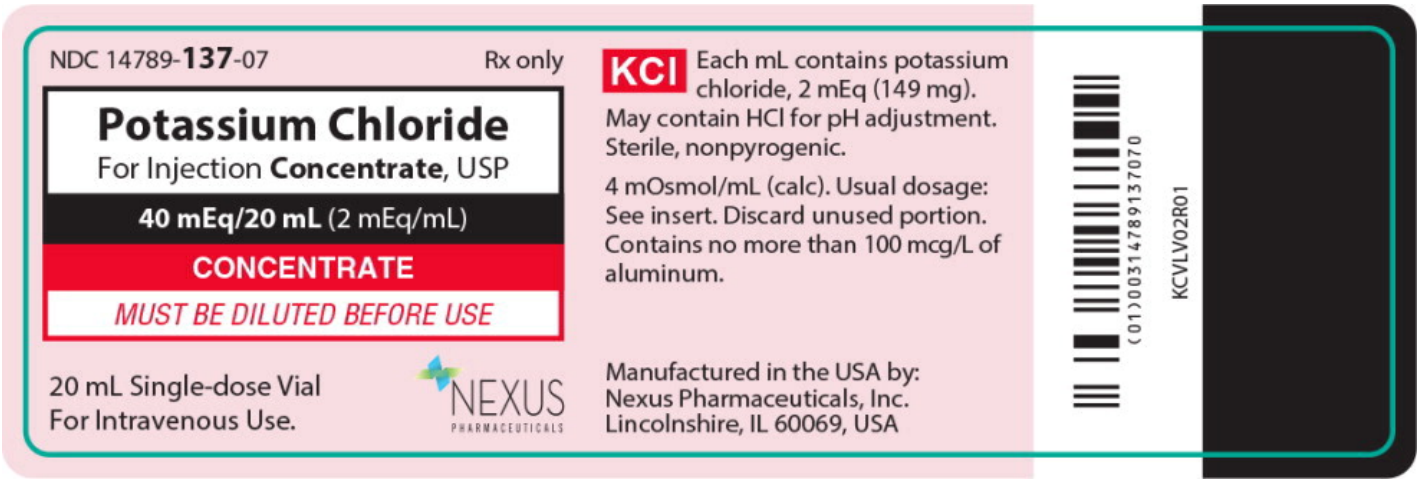
**CONCENTRATE**

*MUST BE DILUTED BEFORE USE*

20 mL Single-dose Vial

For Intravenous Use.

NEXUS
PHARMACEUTICALS




## POTASSIUM CHLORIDE

potassium chloride injection

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:14789-136 |
| **Route of Administration** | INTRAVENOUS | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **Potassium Chloride** (UNII: 660YQ98I10) (Potassium Cation - UNII:295O53K152) | Potassium Chloride | 29.8 mg in 1 mL |

| Packaging | | | | |
|---|---|---|---|---|

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| 1 | NDC:14789-136-05 | 25 in 1 CARTON | 09/12/2023 | |
| 1 | NDC:14789-136-07 | 10 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA217704 | 09/12/2023 | |

# POTASSIUM CHLORIDE

potassium chloride injection

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:14789-137 |
| **Route of Administration** | INTRAVENOUS | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **Potassium Chloride** (UNII: 660YQ98I10) (Potassium Cation - UNII:295O53K152) | Potassium Chloride | 29.8 mg in 1 mL |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| 1 | NDC:14789-137-05 | 25 in 1 CARTON | 09/12/2023 | |
| 1 | NDC:14789-137-07 | 20 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA217704 | 09/12/2023 | |

## Labeler - Nexus Pharamaceuticals Inc. (620714787)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|

| | | | |
|---|---|---|---|
| Nexus Pharmaceuticals Inc | | 620714787 | ANALYSIS(14789-136, 14789-137) |