POTASSIUM ACETATE- potassium acetate injection, solution, concentrate
Exela Pharma Sciences, LLC

Potassium Acetate Injection USP

POTASSIUM ACETATE INJECTION, USP
40 mEq in 20 mL
(2 mEq K+ and 2 mEq CH_3COO^-/mL)
For additive use only after dilution in intravenous fluids
USP Type I Glass Vial
Rx Only

DESCRIPTION

Potassium Acetate Injection, USP, 40 mEq (2 mEq/mL) is a sterile, nonpyrogenic, concentrated solution of potassium acetate in water for injection. The solution is administered after dilution by the intravenous route as an electrolyte replenisher. *It must not be administered undiluted.*

Each 20 mL vial contains 3.93 g of potassium acetate which provides 40 mEq each of potassium (K+) and acetate ($CH3COO^-$). It contains no bacteriostat, antimicrobial agent or added buffer. May contain acetic acid for pH adjustment. pH 6.2 (5.5 to 8.0). The osmolar concentration is 4 mOsmol/mL (calc.).

The solution is intended as an alternative to potassium chloride to provide potassium ion (K+) for addition to large volume infusion fluids for intravenous use.

Potassium acetate, USP is chemically designated CH_3COOK, colorless crystals or white crystalline powder very soluble in water.

The vial is fabricated from USP Type I glass.

CLINICAL PHARMACOLOGY

As the principal cation of the intracellular fluid, potassium plays an important role in fluid and electrolyte balance. The normal potassium concentration in the intracellular fluid compartment is about 160 mEq/liter. The normal serum potassium range is 3.5 to 5.0 mEq/liter. The kidney normally regulates potassium balance but does not conserve potassium as well or as promptly as it conserves sodium. The daily turnover of potassium in the normal adult averages 50 to 150 mEq (milliequivalents) and represents 1.5 to 5% of the total potassium content of the body.

Acetate (CH_3COO^-), a source of hydrogen ion acceptors, is an alternate source of bicarbonate (HCO_3^-) by metabolic conversion in the liver. This has been shown to proceed readily, even in the presence of severe liver disease.

INDICATIONS AND USAGE

Potassium Acetate Injection, USP is indicated as a source of potassium, for the addition to large volume intravenous fluids, to prevent or correct hypokalemia 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.

CONTRAINDICATIONS

Potassium administration is contraindicated in patients with severe renal insufficiency or adrenal insufficiency and in diseases where high potassium levels may be encountered.

WARNINGS

Potassium Acetate Injection, USP must be diluted before use.

To avoid potassium intoxication, infuse potassium-containing solutions slowly. Potassium replacement therapy should be monitored whenever possible by continuous or serial electrocardiography (ECG). Serum potassium levels are not necessarily dependable indicators of tissue potassium levels.

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.

Solutions containing acetate ions should be used with great care in patients with metabolic or respiratory alkalosis. Acetate should be administered with great care in those conditions in which there is an increased level or an impaired utilization of this ion, such as severe hepatic insufficiency.

WARNING: 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

Do not administer unless solution is clear and seal is intact. Discard unused portion.
Potassium replacement therapy should be guided primarily by ECG monitoring and secondarily by the serum potassium level.
High plasma concentrations of potassium may cause death by 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.
Solutions containing acetate ion should be used with caution as excess administration may result in metabolic alkalosis.

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

Pediatric Use: The safety and effectiveness of potassium acetate have been established in pediatric patients.

Geriatric Use: An evaluation of current literature revealed no clinical experience identifying differences in response between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Potassium ions are known to be substantially excreted by the kidney, and the risk of toxic reactions may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

ADVERSE REACTIONS

Adverse reactions involve the possibility of potassium intoxication. 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. See WARNINGS and PRECAUTIONS.

OVERDOSAGE

In the event of overdosage, discontinue infusion containing potassium acetate immediately and institute corrective therapy as indicated to reduce elevated serum potassium levels and restore acid-base balance if necessary. See WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS.

DOSAGE AND ADMINISTRATION

Potassium Acetate Injection, USP 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. ECG and serum potassium should be monitored as a guide to dosage. Using aseptic technique, all or part of the contents of one or more vials may be added to other intravenous fluids to provide any desired number of milliequivalents (mEq) of potassium (K^+) with an equal number of milliequivalents of acetate (CH_3COO^-).

Maximum infusion rate: The infusion rate should not exceed 1 mEq/kg/hr.

Normal daily requirements:

Newborn: 2-6 mEq/kg/24 hr.
Children: 2-3 mEq/kg/24 hr.
Adult: 40-80 mEq/24 hr.

Intraosseous infusion can be an alternate route for drug administration when intravenous access is not readily available.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. See PRECAUTIONS.

HOW SUPPLIED

Potassium Acetate Injection, USP, 40 mEq (2 mEq/mL) of K^+ is supplied in a carton of 25, 20 mL partial-fill single-dose fliptop glass vials.

Each container is partially filled to provide air space for complete vacuum withdrawal of the contents into the I.V. container.

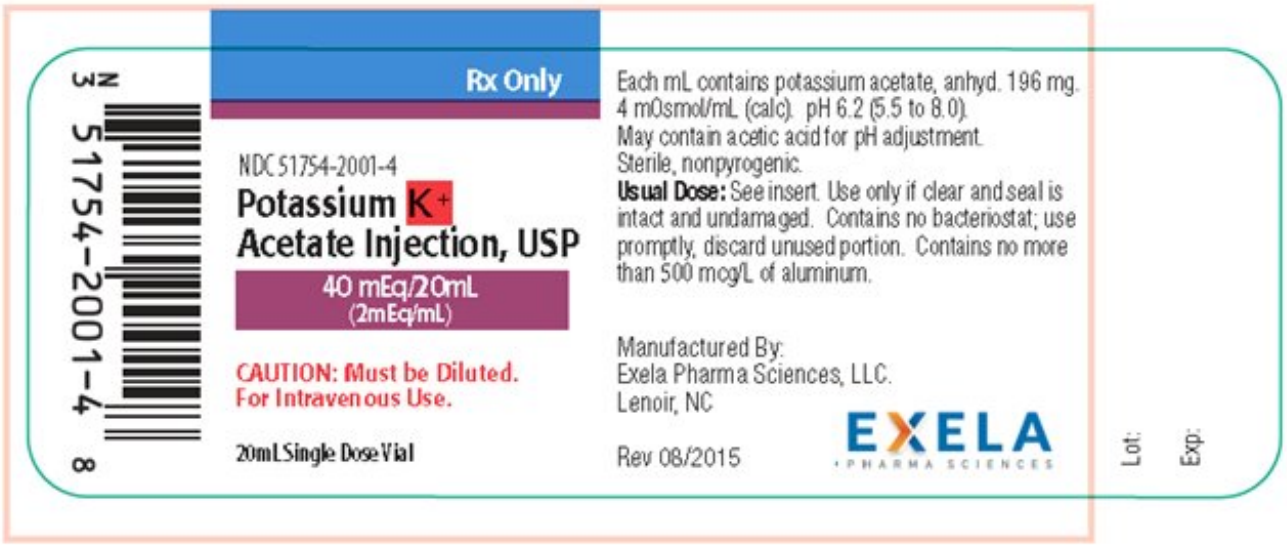
Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.]

Revised: October 2015

Exela Pharma Sciences, LLC.

Lenoir, NC 28645 USA

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL-Vial Label



NDC 51754-2001-4 Rx Only

Potassium K^+

Acetate Injection, USP

40 mEq/20 mL

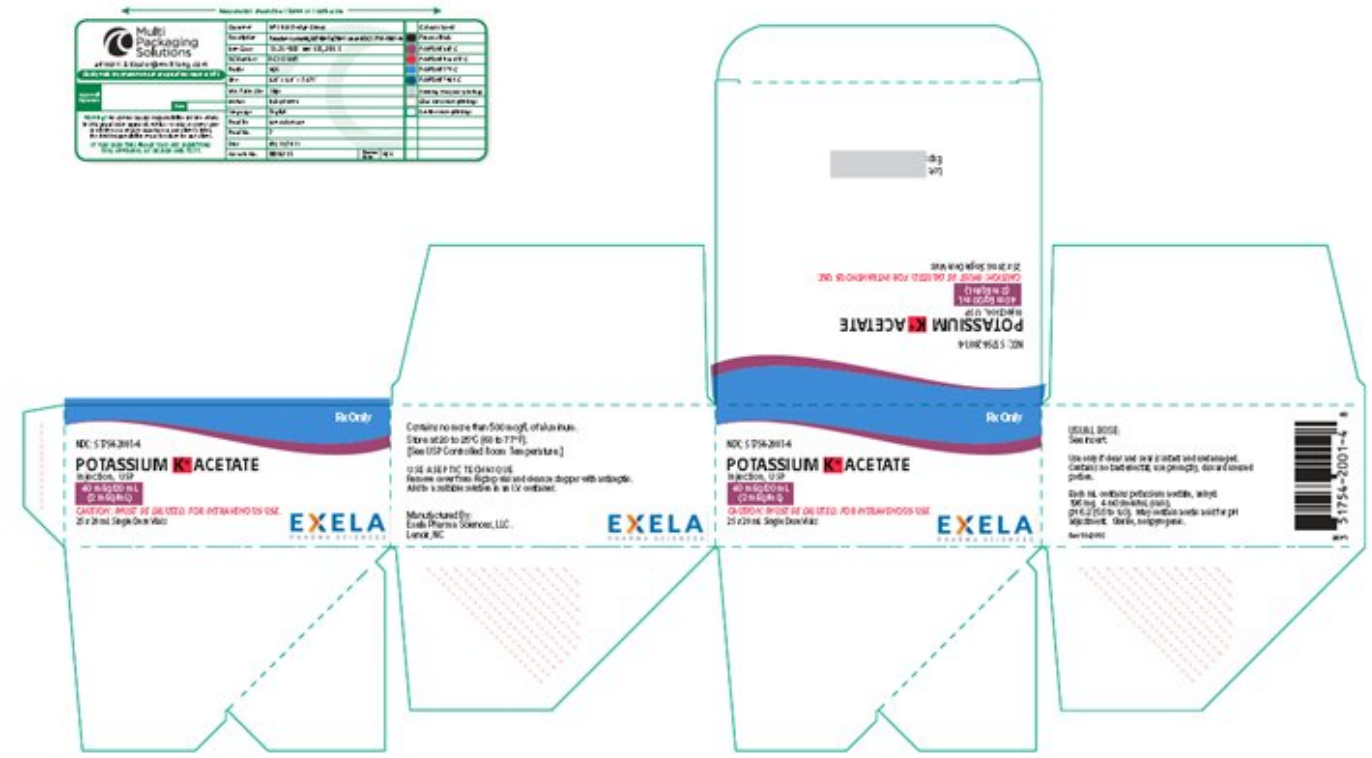
(2mEq/mL)

CAUTION: Must be Diluted.

For Intravenous Use.

20 mL Single Dose Vial

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL-Carton Label



NDC 51754-2001-4 Rx Only

Potassium K^+ Acetate

Injection, USP

40 mEq/20 mL

(2mEq/mL)

CAUTION: Must be Diluted. For Intravenous Use.

25 x 20 mL Single Dose Vials

POTASSIUM ACETATE

potassium acetate injection, solution, concentrate

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51754-2001
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POTASSIUM ACETATE (UNII: M9119 11U02) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM ACETATE	3.93 g in 20 mL

Inactive Ingredients	
Ingredient Name	**Strength**

WATER (UNII: 059QF0KO0R)	
ACETIC ACID (UNII: Q40Q9N063P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51754-2001-4	25 in 1 CARTON	01/07/2016	
1		20 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206203	01/07/2016	

Labeler - Exela Pharma Sciences, LLC (831274399)

Registrant - Exela Pharma Sciences, LLC (831274399)

Establishment

Name	Address	ID/FEI	Business Operations
Exela Pharma Sciences, LLC		831274399	MANUFACTURE(51754-2001)

Revised: 1/2016 Exela Pharma Sciences, LLC