POTASSIUM ACETATE- potassium acetate injection, solution, concentrate
Hospira, Inc.

Potassium Acetate
Injection, USP

100 mEq/50 mL

(2 mEq/mL)

(2 mEq K^+/mL and 2 mEq CH_3COO^-/mL)

Pharmacy Bulk Package –
Not for Direct Infusion.

CONCENTRATED SOLUTION –

FOR INTRAVENOUS USE ONLY AFTER

DILUTION AND THOROUGH MIXING.

Glass Fliptop Vial

Rx only

DESCRIPTION

Potassium Acetate Injection, USP (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 mL contains 196 mg of potassium acetate which provides 2 mEq each of potassium (K^+) and acetate (CH_3COO^-). The solution may contain acetic acid for pH adjustment. The pH is 6.2 (range: 5.5 to 8.0). The osmolar concentration is 4 mOsmol/mL (calc.); specific gravity is 1.089.

The Pharmacy Bulk Package is a sterile dosage which contains multiple single doses for use only in a pharmacy bulk admixture program.

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, and is comprised of colorless crystals or a white crystalline powder that is very soluble in water.

The Pharmacy Bulk Package is designed for use with manual, gravity flow operations and automated compounding devices for preparing sterile parenteral nutrient admixtures. The Pharmacy Bulk Package contains no bacteriostat, antimicrobial agent, or added buffer. Multiple single doses may be dispensed during continual aliquoting operations.

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 (2 mEq/mL) 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 (2 mEq/mL) 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

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 (2 mEq/mL) in the Pharmacy Bulk Package is designed for use with manual, gravity flow operations and automated compounding devices for preparing sterile nutrient admixtures.

Potassium Acetate Injection, USP (2 mEq/mL) 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**.)

Directions for Dispensing From Pharmacy Bulk Package

The Pharmacy Bulk Package is for use in the Pharmacy Admixtures Service only. For hanger application, peel off the paper liner from both ends of the tape hanger to expose 3/4 inch long adhesive portions. Adhere each end to the label on the bottle. The vials should be suspended as a unit in the laminar flow hood.

A single entry through the vial closure should be made with a sterile dispensing set or transfer device. Transfer individual doses to appropriate intravenous infusion solutions. Use of a syringe with needle is not recommended as it may cause leakage and multiple entries will increase the potential of microbial and particulate contamination.

The above process should be carried out under a laminar flow hood using aseptic technique. Discard any unused portion within 4 hours after initial closure entry.

HOW SUPPLIED

Potassium Acetate Injection, USP is a Pharmacy Bulk Package which provides multiple single doses for continuous admixture compounding procedures is supplied as follows:

Unit of Sale	Concentration	Each
NDC 0409-3294-51 Carton of 25	100 mEq/50 mL (2 mEq/mL)	NDC 0409-3294-61 Glass Fliptop Vial

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

Distributed by Hospira, Inc., Lake Forest, IL 60045 USA

LAB-0903-2.0

9/2017

PRINCIPAL DISPLAY PANEL - 50 mL Vial Label

50 mL

K^+

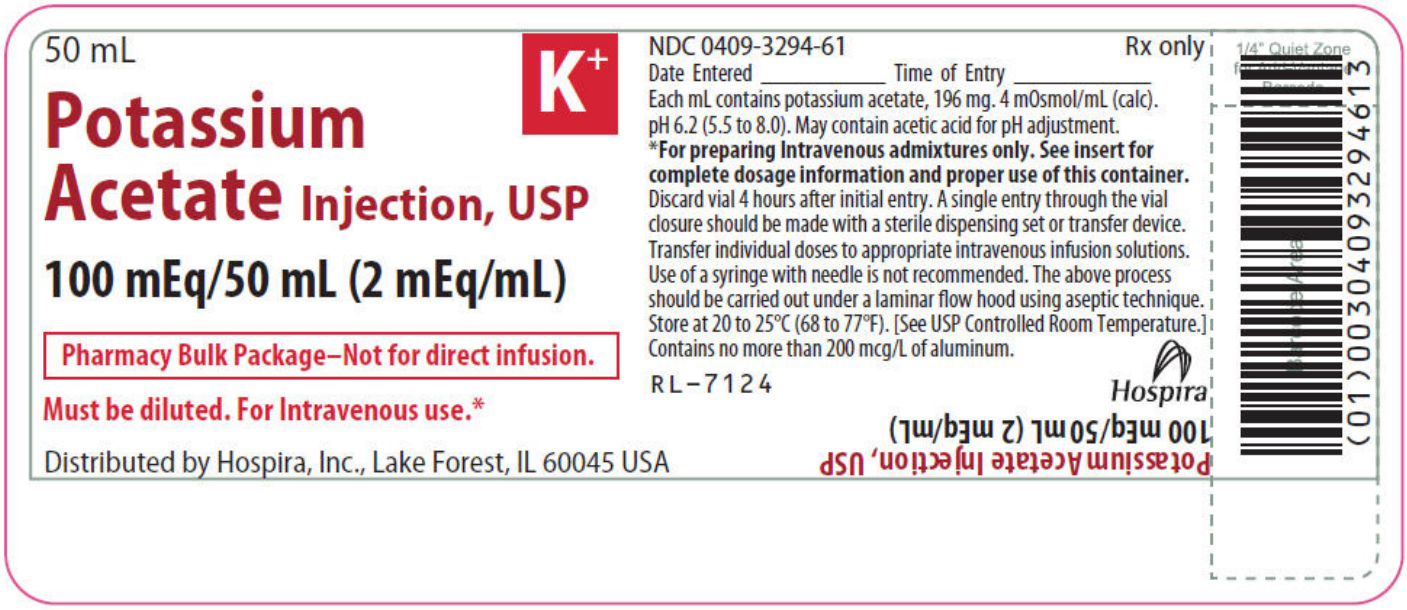
Potassium
Acetate Injection, USP

100 mEq/50 mL (2 mEq/mL)

Pharmacy Bulk Package–Not for direct infusion.

Must be diluted. For Intravenous use.*

Distributed by Hospira, Inc., Lake Forest, IL 60045 USA



PRINCIPAL DISPLAY PANEL - 50 mL Vial Tray

50 mL

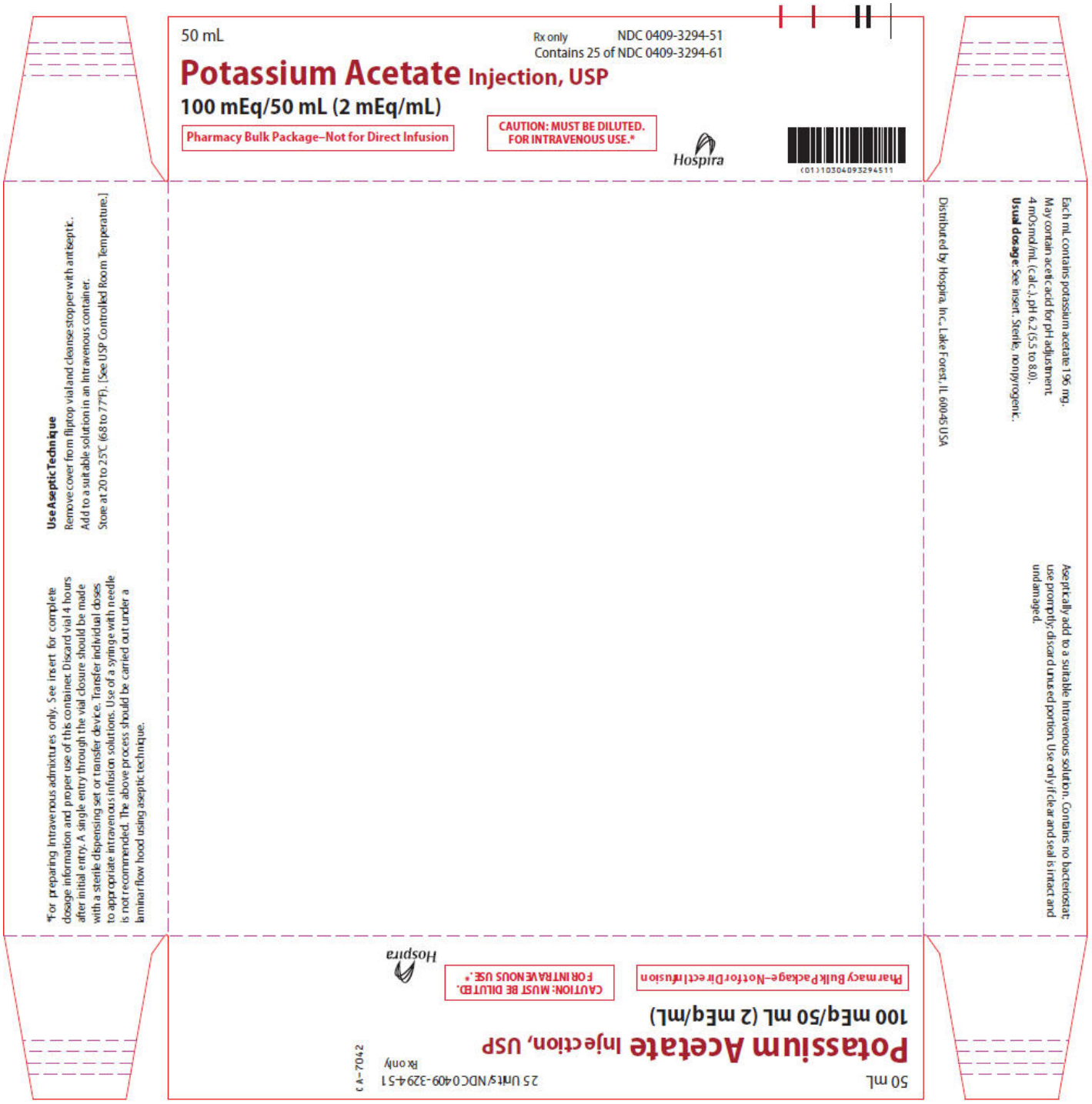
Rx only
NDC 0409-3294-51
Contains 25 of NDC 0409-3294-61

Potassium Acetate Injection, USP
100 mEq/50 mL (2 mEq/mL)

Pharmacy Bulk Package–Not for Direct Infusion

CAUTION: MUST BE DILUTED.
FOR INTRAVENOUS USE.*

Hospira



POTASSIUM ACETATE

potassium acetate injection, solution, concentrate

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0409-3294
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

POTASSIUM ACETATE (UNII: M911911U02) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM ACETATE	196.3 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ACETIC ACID (UNII: Q40Q9N063P)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0409-3294-51	25 in 1 TRAY	07/05/2005	
1	NDC:0409-3294-61	50 mL in 1 VIAL, PHARMACY BULK PACKAGE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018896	07/05/2005	

Labeler - Hospira, Inc. (141588017)

Establishment

Name	Address	ID/FEI	Business Operations
Hospira, Inc.		093132819	ANALYSIS(0409-3294) , LABEL(0409-3294) , MANUFACTURE(0409-3294) , PACK(0409-3294)

Establishment

Name	Address	ID/FEI	Business Operations
Hospira, Inc.		827731089	ANALYSIS(0409-3294)

Establishment

Name	Address	ID/FEI	Business Operations
Pfizer Healthcare India Private Limited		860037912	ANALYSIS(0409-3294) , LABEL(0409-3294) , MANUFACTURE(0409-3294) , PACK(0409-3294)

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