POTASSIUM ACETATE

POTASSIUM ACETATE
Injection, 40 mEq in 20 mL
Plastic Vial

USPI

Reference Market: USA
AfME Markets using same as LPD: Saudi Arabia

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Potassium Acetate 40 mEq in 20 mL injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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.. 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 CH3COOK, colorless crystals or white crystalline powder very soluble in water.

The semi-rigid vial is fabricated from a specially formulated polyolefin. It is a copolymer of ethylene and propylene. The safety of the plastic has been confirmed by tests in animals according to USP biological standards for plastic containers. The container requires no vapor barrier to maintain the proper drug concentration.

3. PHARMACEUTICAL FORM

Injection, USP for additive use only after dilution in intravenous fluids .

Each 20 mL vial contains 3.93 g of potassium acetate which provides 40 mEq each of potassium (K^+) and acetate (CH_3COO^-). 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.).

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Potassium Acetate Injection, USP, 40 mEq 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.

4.2 Posology and method of administration

Potassium Acetate Injection, USP, 40 mEq 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 ($CH3COO^-$). 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.)

4.3 Contraindications

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

4.4 Special warnings and precautions for use

Potassium Acetate Injection, USP, 40 mEq 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.

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.

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.

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.

4.5 Interaction with other medicinal products and other forms of interaction

Not applicable

4.6 Fertility, pregnancy and lactation

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.

4.7 Effects on ability to drive and use machines

Not Applicable

4.8 Undesirable effects

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**.)

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after marketing authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions according to their local country requierements.

To reports any side effect(s):

- ***Saudi Arabia:***

– The National Pharmacovigilance and Drug Safety Centre (NPC)
- Fax: +966-11-205-7662
- Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340.
- Toll free phone: 8002490000
- E-mail: npc.drug@sfda.gov.sa
- Website: www.sfda.gov.sa/npc

4.9 Overdose

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**.)

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic properties

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.

5.3 Preclinical safety data

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Each 20 mL vial contains 3.93 g of potassium acetate which provides 40 mEq each of potassium (K+) and acetate ($CH3COO^-$).

May contain acetic acid for pH adjustment.

This product contains aluminum that may be toxic.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Do not use this medicine after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

Shelf life: 24 months.

6.4 Special precautions for storage

Keep out of the sight and reach of children.

Store at 20 to 25ºC (68 to 77ºF).

6.5 Nature and contents of container

Potassium Acetate Injection, USP is supplied as follows:

Unit of Sale	Concentration	Each
Carton of 25	40 mEq/20 mL (2 mEq/mL)	Single-Dose Fliptop Vial

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

Each 20 mL vial contains 3.93 g of potassium acetate which provides 40 mEq each of potassium (K^+) and acetate (CH_3COO^-). 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.).

Keep out of the sight and reach of children.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment**.**

7. FURTHER INFORMATION

MARKETING AUTHORISATION HOLDER

Hospira, Inc., Lake Forest, IL 60045 USA

8. MANUFACUTRED BY

Hospira, Rocky Mount, USA

9. DATE OF REVISION OF THE TEXT

September/2017