Prescribing Information

POTASSIUM ACETATE INJECTION USP
(Potassium Acetate 39.2% w/v)

Electrolyte Replenisher

Not for direct injection. Must be diluted before use.

Not for direct dispensing to the patient.

Summary Product Information

Route of administration	Dosage form/strength	Clinically relevant non-medicinal ingredients
Intravenous after dilution	Flip-top vials of 50 mL potassium acetate 4 mEq/mL	None

Indications:

Potassium Acetate Injection USP should be used only under medical supervision.

Potassium Acetate Injection USP is for addition to large volume IV fluids for replacement and maintenance of normokalemia when a source of acetate is also required or when potassium chloride cannot be used.

Contraindications

Hyperkalemia;
Diseases or conditions that predispose to hyperkalemia.

Warnings and precautions:

Potassium Acetate Injection USP must be diluted before use.

Intravenous fluids given peripherally should not contain more than 20 mmol/L potassium. Potassium should not be infused at a rate greater than 10 mmol/hour without cardiac monitoring in a critical care setting. Serum potassium concentration is not a reliable indicator of total body content of potassium.

Abnormally high or low blood potassium concentrations are associated with toxicity which may be severe and potentially lethal.

In situations where a large potassium deficit needs to be replenished urgently, continuous cardiac monitoring in addition to frequent serum potassium concentration measurements should be used to reduce the risk of cardiac arrhythmias and sudden death.

Solutions or products containing acetate ion should be used with caution in patients with metabolic or respiratory alkalosis. Acetate should be administered with great care in

conditions in which there is impaired utilization of acetate, such as severe hepatic insufficiency.

Use with caution in the presence of cardiac disease, particularly in digitalized patients or in the presence of renal disease.

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/L. The normal serum potassium range is 3.5 to 5 mEq/L. Potassium homeostasis is regulated chiefly by the kidney. The daily turnover of potassium in the normal adult averages 50 to 150 mEq 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^-) and the major source of acetoacetate entering the Krebs cycle. Acetate is metabolized in the liver and in muscle and other tissues.

Adverse Reactions:

Administration of potassium acetate may lead to hyperkalemia if it is infused faster than potassium can be delivered to the intracellular fluid.

The signs and symptoms of hyperkalemia 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 the P waves, spreading and slurring of the QRS complex by development of a biphasic curve and cardiac arrest. (See **Warnings and Precautions**)

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following three ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701C
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at: www.healthcanada.gc.ca/medeffect

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

Overdose:

In the event of overdosage, discontinue infusion containing potassium immediately. If ECG changes are present, give calcium chloride or calcium gluconate immediately. Therapy to move potassium into the intracellular compartment, such as glucose and insulin may be used while preparing additional treatment specifically intended to remove potassium from the body, such as dialysis or ion exchange resins. If concurrent electrolyte or acid base abnormalities are present, these must also be addressed.

Dosage:

Potassium acetate is administered i.v. **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 i.v. fluids to provide an appropriate number of mEq of potassium with an equal number of mEq of acetate.

Potassium Acetate Injection USP in vials should be clear, particle free and present no leaks. The diluted solution for final administration should be checked for clarity, haziness and be particle free. The product does not contain any preservatives. It should be used immediately. Discard unused portion. Not for direct injection. Pharmacy use only.

Composition:

Each mL of sterile, nonpyrogenic, concentrated solution contains: Potassium Acetate Anhydrous 392 mg (4 mmol equivalent to 4 mEq) and Water for Injection USP. Also contains Acetic Acid for pH adjustment (5.5 to 8). Osmolarity: 8 mOsm/mL. Contains no bacteriostatic, antimicrobial or added buffering agents.

Supplied: Flip-top glass USP Type I vials of 50 mL, boxes of 10 with rubber stoppers and aluminium seals.

How to store it: Store between 15 and 30°C. Do not freeze.

More information: This document, prepared for health professionals can be obtained by contacting the sponsor, Omega Laboratories Ltd., at:

By telephone: (514) 335-0310 or 1-800-363-0584

By mail: Omega Laboratories Ltd.
11 177 Hamon
Montreal, QC H3M 3A2

By internet: www.omegalaboratory.com

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