

POTASSIUM CHLORIDE IN SODIUM CHLORIDE- sodium chloride and potassium chloride injection, solution
ICU Medical, Inc.

Potassium Chloride in Sodium Chloride Injection, USP

Flexible Plastic Container

Rx only

DESCRIPTION

Potassium Chloride in Sodium Chloride Injection, USP is a sterile, nonpyrogenic, solution for fluid and electrolyte replenishment in a single dose container for intravenous administration. It contains no antimicrobial agents. Composition, osmolarity, pH and ionic concentration are shown in Table 1.

Table 1:

20 mEq/ L Potassium Chloride in 0.45% Sodium Chloride Inj., USP		Composition (g/L)		Calculated Osmolarity (mOsmol/L)	pH (range)	Ionic Concentrations (mEq/L)		
NDC No.	Size (mL)	Sodium Chloride (NaCl)	Potassium Chloride (KCl)			Sodium (Na+)	Potassium (K+)	Chloride (Cl-)
0409-9257-39	1000	4.5	1.49	194	4.8 (3.5 to 6.5)	77	20	97
0990-9257-39	1000	4.5	1.49	194	4.8 (3.5 to 6.5)	77	20	97

The flexible plastic container is fabricated from a specially formulated polyvinyl chloride (PL 146 Plastic). The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution significantly. Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts within the expiration period. However, the safety of the plastic has been confirmed in tests in animals according to USP biological tests for plastic containers.

CLINICAL PHARMACOLOGY

Potassium Chloride in Sodium Chloride Injection, USP has value as a source of water and electrolytes. It is capable of inducing diuresis depending on the clinical condition of the patient.

INDICATIONS AND USAGE

Potassium Chloride in Sodium Chloride Injection, USP is indicated as a source of water and electrolytes.

CONTRAINDICATIONS

None known.

WARNINGS

Potassium Chloride in Sodium Chloride Injection, USP should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency and in clinical states in which there exists edema with sodium retention.

Potassium Chloride in Sodium Chloride Injection, USP 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.

The intravenous administration of Potassium Chloride in Sodium Chloride Injection, USP can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injection. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

In patients with diminished renal function, administration of Potassium Chloride in Sodium Chloride Injection, USP may result in sodium or potassium retention.

Potassium salts should never be administered by IV push.

PRECAUTIONS

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.

Caution must be exercised in the administration of Potassium Chloride in Sodium Chloride Injection, USP to patients receiving corticosteroids or corticotropin.

Pregnancy: Teratogenic Effects

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

Carcinogenesis, mutagenesis, impairment of fertility

Studies with Potassium Chloride in Sodium Chloride Injection, USP have not been performed to evaluate carcinogenic potential, mutagenic potential or effects on fertility.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Potassium Chloride in Sodium Chloride Injection, USP is administered to a nursing mother.

Pediatric Use

Safety and effectiveness of Potassium Chloride in Sodium Chloride Injection, USP in pediatric patients have not been established by adequate and well-controlled studies. However, the use of potassium chloride injection in pediatric patients to treat potassium deficiency states when oral replacement therapy is not feasible is referenced in the medical literature.

For patients receiving potassium supplement at greater than maintenance rates, frequent monitoring of serum potassium levels and serial EKGs are recommended.

Geriatric Use

Clinical studies of Potassium Chloride in Sodium Chloride Injection, USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the 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.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug 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.

Do not administer unless solution is clear and seal is intact.

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 and hypervolemia.

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.

Dosage and Administration

As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Use of final filter is recommended during administration of all parenteral solutions, where possible.

Potassium Chloride in Sodium Chloride Injection, USP in flexible plastic containers is intended for intravenous administration.

Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

INSTRUCTIONS FOR USE

To Open

Tear outer wrap at notch and remove solution container. If supplemental medication is desired, follow directions below before preparing for administration. Some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually.

To Add Medication

1. Prepare additive port.
2. Using aseptic technique and an additive delivery needle of appropriate length, puncture resealable additive port at target area, inner diaphragm and inject. Withdraw needle after injecting medication.
3. The additive port may be protected by covering with an additive cap.
4. Mix container contents thoroughly.

Preparation for Administration

(Use aseptic technique)

1. Close flow control clamp of administration set.
2. Remove cover from outlet port at bottom of container.
3. Insert piercing pin of administration set into port with a twisting motion until the set is firmly seated.
NOTE: See full directions on administration set carton.
4. Suspend container from hanger.
5. Squeeze and release drip chamber to establish proper fluid level in chamber.
6. Open flow control clamp and clear air from set. Close clamp.
7. Attach set to venipuncture device. If device is not indwelling, prime and make venipuncture.
8. Regulate rate of administration with flow control clamp.

WARNING: Do not use flexible container in series connections.

HOW SUPPLIED

20 mEq/L Potassium Chloride in 0.45% Sodium Chloride Injection, USP is supplied in 1000 mL single-dose flexible plastic containers (NDC 0409-9257-39) (NDC 0990-9257-39).

ICU Medical is transitioning NDC codes from the "0409" to a "0990" labeler code. Both NDC codes are expected to be in the market for a period of time.

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

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