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

Potassium Chloride in Sodium Chloride Injection, USP is contraindicated in patients with:

- Known hypersensitivity to potassium chloride and/or sodium chloride (see WARNINGS).
- Clinically significant hyperkalemia (see WARNINGS).

WARNINGS

Hypersensitivity

Hypersensitivity and infusion reactions, including anaphylaxis and chills, have been reported with products containing potassium chloride and sodium chloride. Stop the infusion immediately if signs or symptoms of a hypersensitivity or infusion reaction develops. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

Electrolyte Imbalances

Hyperkalemia

Potassium-containing solutions, including Potassium Chloride in Sodium Chloride Injection, USP may increase the risk of hyperkalemia. Hyperkalemia can be asymptomatic and manifest only by increased serum potassium concentrations and/or characteristic electrocardiographic (ECG) changes. Cardiac conduction disorders (including complete heart block) and other cardiac arrhythmias, some fatal, can develop at any time during hyperkalemia. Continuous electrocardiogram (ECG) monitoring may be necessary to aid in the detection of cardiac arrhythmias due to hyperkalemia (see ADVERSE REACTIONS).

To avoid life threatening hyperkalemia, do not administer Potassium Chloride in Sodium Chloride Injection, USP as an intravenous push (i.e., intravenous injection manually with a syringe connected to the intravenous access) without a quantitative infusion device.

Patients at increased risk of developing hyperkalemia and cardiac arrhythmias include those:

- with conditions predisposing to hyperkalemia and/or associated with increased sensitivity to potassium, such as patients with severe renal impairment, acute dehydration, extensive tissue injury or burns, certain cardiac disorders such as congestive heart failure or atrioventricular (AV) block (especially if they receive digoxin).
- who are at risk of experiencing hyperosmolality, acidosis, or undergoing correction of alkalosis (conditions associated with a shift of potassium from intracellular to extracellular space).

- treated concurrently or recently with agents or products that can cause or increase the risk of hyperkalemia (see DRUG INTERACTIONS).
- with cardiac arrhythmias.

Avoid use of Potassium Chloride in Sodium Chloride Injection, USP in patients with, or at risk for, hyperkalemia. If use cannot be avoided, use a product with a low amount of potassium chloride, infuse slowly and monitor serum potassium concentrations and ECGs.

Hypernatremia and Hyperchloremia

Electrolyte imbalances such as hypernatremia, hyperchloremia, and metabolic acidosis may occur with Potassium Chloride in Sodium Chloride Injection, USP.

Conditions that may increase the risk of hypernatremia, fluid overload and edema (central and peripheral), include patients with: primary hyperaldosteronism; secondary hyperaldosteronism associated with, for example, hypertension, congestive heart failure, liver disease (including cirrhosis), renal disease (including renal artery stenosis, nephrosclerosis); and pre-eclampsia.

Certain medications, such as corticosteroids or corticotropin, may also increase risk of sodium and fluid retention, see DRUG INTERACTIONS.

Avoid Potassium Chloride in Sodium Chloride Injection, USP in patients with, or at risk for, hypernatremia or hyperchloremia. If use cannot be avoided, monitor serum sodium and chloride concentrations and acid-base balance.

Rapid correction of hypernatremia is potentially dangerous with risk of serious neurologic complications. Excessively rapid correction of hypernatremia is also associated with a risk for serious neurologic complications such as osmotic demyelination syndrome (ODS) with risk of seizures and cerebral edema.

Hyponatremia

Potassium Chloride in Sodium Chloride Injection, USP may cause hyponatremia.

Hyponatremia can lead to acute hyponatremic encephalopathy characterized by headache, nausea, seizures, lethargy, and vomiting. Patients with brain edema are at particular risk of severe, irreversible and life-threatening brain injury.

The risk of hospital-acquired hyponatremia is increased in patients with cardiac or pulmonary failure, and in patients with non-osmotic vasopressin release (including SIADH) treated with high volume of hypotonic Potassium Chloride in Sodium Chloride Injection, USP.

The risk for hyponatremia is increased in pediatric patients, elderly patients, postoperative patients, those with psychogenic polydipsia, and in patients treated with medications that increase the risk of hyponatremia (such as diuretics, certain antiepileptic and psychotropic medications). See DRUG INTERACTIONS.

Patients at increased risk for developing complications of hyponatremia such as hyponatremic encephalopathy, include pediatric patients, women (in particular, premenopausal women), patients with hypoxemia, and patients with underlying central nervous system disease. Avoid Potassium Chloride in Sodium Chloride Injection, USP in patients with or at risk for hyponatremia. If use cannot be avoided, monitor serum

sodium concentrations.

Rapid correction of hyponatremia is potentially dangerous with risk of serious neurologic complications. Brain adaptations reducing risk of cerebral edema make the brain vulnerable to injury when chronic hyponatremia is too rapidly corrected, which is known as osmotic demyelination syndrome (ODS). To avoid complications, monitor serum sodium and chloride concentrations, fluid status, acid-base balance, and signs of neurologic complications.

Fluid Overload

Depending on the volume and rate of infusion, and the patient's underlying clinical condition, the intravenous administration of Potassium Chloride in Sodium Chloride Injection, USP can cause electrolyte disturbances such as overhydration/hypervolemia and congested states including central (e.g., pulmonary edema) and peripheral edema.

Avoid Potassium Chloride in Sodium Chloride Injection, USP in patients with or at risk for fluid and/or solute overloading. If use cannot be avoided, monitor fluid balance, electrolyte concentrations and acid base balance as needed and especially during prolonged use.

PRECAUTIONS

Patients with Severe Renal Impairment

Administration of sodium and potassium in patients with or at risk of severe renal impairment, may result in hypernatremia, hyperkalemia and/or fluid overload (see WARNINGS). Avoid Potassium Chloride in Sodium Chloride Injection, USP in patients with severe renal impairment. If use cannot be avoided, monitor patients with severe renal impairment for development of these adverse reactions.

Drug Interactions

Lithium

Renal sodium and lithium clearance may be increased during administration of Potassium Chloride in Sodium Chloride Injection, USP and result in decreased lithium concentrations. Monitor serum lithium concentrations during concomitant use.

Other Products that Cause Hyperkalemia

Administration of Potassium Chloride in Sodium Chloride Injection, USP in patients treated concurrently or recently with products that are associated with hyperkalemia increases the risk of severe and potentially fatal hyperkalemia, in particular in the presence of other risk factors for hyperkalemia. Avoid use of Potassium Chloride in Sodium Chloride Injection, USP in patients receiving such products (e.g., potassium sparing diuretics, angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, or the immunosuppressants cyclosporine and tacrolimus). If use cannot be avoided, monitor serum potassium concentrations.

Other Products that Affect Fluid and/or Electrolyte Balance

Administration of Potassium Chloride in Sodium Chloride Injection, USP in patients treated concomitantly with medications associated with sodium and fluid retention may increase the risk of hypernatremia and volume overload. Avoid use of Potassium Chloride in Sodium Chloride Injection, USP in patients receiving such products, such as corticosteroids or corticotropin. If use cannot be avoided, monitor serum electrolytes, fluid balance, and acid-base balance.

Other Drugs that Increase the Risk of Hyponatremia

Administration of Potassium Chloride in Sodium Chloride Injection, USP in patients treated concomitantly with medications associated with hyponatremia may increase the risk of developing hyponatremia.

Avoid use of Potassium Chloride in Sodium Chloride Injection, USP in patients receiving products, such as diuretics, and certain antiepileptic and psychotropic medications. Drugs that increase the vasopressin effect reduce renal electrolyte free water excretion and may also increase the risk of hyponatremia following treatment with intravenous fluids. If use cannot be avoided, monitor serum sodium concentrations.

Pregnancy

There are no adequate and well controlled studies from the use of Potassium Chloride in Sodium Chloride Injection, USP in pregnant or lactating women and animal reproduction studies have not been conducted with this drug. Therefore, 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 the potential benefit justifies the potential risk to the fetus.

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

The use of Potassium Chloride in Sodium Chloride Injection, USP in pediatric patients is based on clinical practice. (See DOSAGE AND ADMINISTRATION). Safety and effectiveness of Potassium Chloride in Sodium Chloride Injection, USP in pediatric patients have not been established by adequate and well-controlled studies.

Pediatric patients are at increased risk of developing hyponatremia as well as for developing encephalopathy as a complication of hyponatremia (see WARNINGS).

Geriatric Use

Geriatric patients are at increased risk of developing electrolyte imbalances. Potassium Chloride in Sodium Chloride Injection, USP 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. Therefore, 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. Consider monitoring renal function in elderly patients.

ADVERSE REACTIONS

The following adverse reactions associated with the use of Potassium Chloride in Sodium Chloride Injection, USP were identified in clinical trials or postmarketing reports. Because postmarketing reactions were reported voluntarily from a population of uncertain size, it is not always possible to estimate their frequency, reliably, or to establish a causal relationship to drug exposure.

- General disorders and administration site conditions: Chills, and infusion site pain. Hypersensitivity reactions: generalized papules and erythema, rash, fever, vomiting, hypertension, tachycardia.
- Metabolism and nutrition disorders: Hyperkalemia, hyponatremia, hypernatremia, hyperchloremia acidosis, fluid overload.
- Cardiac disorders: Cardiac arrest as a manifestation of rapid intravenous administration and/or of hyperkalemia.
- Nervous System Disorders: Hyponatremic encephalopathy.

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.

OVERDOSAGE

An increased infusion rate of Potassium Chloride in Sodium Chloride Injection, USP can cause:

- hyperkalemia, manifestations may include disturbances in cardiac conduction and arrhythmias, including bradycardia, heart block, asystole, ventricular tachycardia, ventricular fibrillation.

The presence of any ECG findings that are suspected to be caused by hyperkalemia should be considered a medical emergency.

If hyperkalemia is present or suspected, discontinue the infusion immediately and institute close ECG, laboratory and other monitoring and, as necessary, corrective therapy to reduce serum potassium concentrations.

Muscle weakness (up to and including muscular and respiratory paralysis, paresthesia of extremities) may occur as a complication of hyperkalemia.

- hyponatremia, manifestations may include seizures, coma, cerebral edema and death).
- hypernatremia, especially in patients with severe renal impairment.
- hypotension.
- gastrointestinal symptoms (ileus, nausea, vomiting, abdominal pain).
- fluid overload (which can lead to central and/or peripheral edema). See WARNINGS and ADVERSE REACTIONS.

When assessing an overdose, any additives in the solution must also be considered. The effects of an overdose may require immediate medical attention and treatment.

Interventions include discontinuation of Potassium Chloride in Sodium Chloride Injection,

USP administration, dose reduction, and other measures as indicated for the specific clinical constellation (e.g., monitoring of fluid balance, electrolyte concentrations and acid base balance).

Dosage and Administration

Important Administration Instructions

- Potassium Chloride in Sodium Chloride Injection, USP is intended for intravenous infusion using sterile equipment.
- To avoid life threatening hyperkalemia, do not administer Potassium Chloride in Sodium Chloride Injection, USP as an intravenous push (i.e., intravenous injection manually with a syringe connected to the intravenous access) without a quantitative infusion device (see WARNINGS).
- Do not connect flexible plastic containers in series in order to avoid air embolism due to possible residual air contained in the primary container.
- Set the vent to the closed position on a vented intravenous administration set to prevent air embolism.
- Use a dedicated line without any connections to avoid air embolism.
- Do not pressurize intravenous solutions contained in flexible plastic containers to increase flow rates in order to avoid air embolism due to incomplete evacuation of residual air in the container.
- The choice of a central or peripheral venous route of infusion should depend on the osmolarity of the final infusate. Solutions with osmolarity of greater than or equal to approximately 900 mOsm/L must be infused through a central catheter.
- Prior to infusion, visually inspect the solution for particulate matter and discoloration. The solution should be clear and there should be no precipitates. Do not administer unless solution is clear and container is undamaged.
- Use of final filter is recommended during administration of all parenteral solutions, where possible.

Dosing Information

The choice of the specific potassium chloride and sodium chloride formulation, dosage, volume, rate and duration of administration is dependent upon the age, weight and clinical and metabolic condition of the patient and concomitant therapy, and administration should be determined by a physician experienced in intravenous fluid therapy.

Additional electrolyte supplementation may be indicated according to the clinical needs of the patient. Additives can be introduced to the container; however, some additives may be incompatible. Evaluate all additions to the plastic container for compatibility and stability of the resulting preparation. Consult with a pharmacist, if available.

If, in the informed judgment of the physician, it is deemed advisable to introduce additives, use aseptic technique. After addition, if there is a discoloration and/or the appearance of precipitates, insoluble complexes or crystals, do not use. Mix thoroughly when additives have been introduced. Do not store solutions containing additives. Discard any unused portion.

Rapid correction of hyponatremia and hypernatremia is potentially dangerous (risk of serious neurologic complications). To avoid complications such as osmotic demyelination

syndrome (ODS) during administration, follow the important administration instructions, monitor serum sodium and chloride concentrations, fluid status, acid-base balance, and signs of neurologic complications.

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.

INSTRUCTIONS FOR USE

For information on risk of air embolism – see PRECAUTIONS.

To Open

Tear outer wrap at notch and remove solution container. If supplemental medication is desired, follow directions below before preparing for administration. Visually inspect the container. If the outlet port protector is damaged, detached, or not present, discard container as solution path sterility may be impaired. 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.

Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

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.

Revised: July, 2022

ICU Medical, Inc., Lake Forest, Illinois, 60045, USA

IFU0000531

PRINCIPAL DISPLAY PANEL - 1000 mL Bag Label

20 mEq POTASSIUM

1000 mL

NDC 0990-9257-39

POTASSIUM
CHLORIDE
in 0.45%
Sodium Chloride
Injection, USP
20
mEq

EACH 100 mL CONTAINS POTASSIUM CHLORIDE 149 mg;
SODIUM CHLORIDE 450 mg IN WATER FOR INJECTION.
ELECTROLYTES PER 1000 mL: POTASSIUM 20 mEq;
SODIUM 77 mEq; CHLORIDE; 97 mEq.
194 mOsmol/LITER (CALC.)
pH 4.8 (3.5 to 6.5)

ADDITIVES MAY BE INCOMPATIBLE. CONSULT WITH
PHARMACIST, IF AVAILABLE. WHEN INTRODUCING
ADDITIVES, USE ASEPTIC TECHNIQUE,
MIX THOROUGHLY AND DO NOT STORE.

SINGLE-DOSE CONTAINER. STORE AT 20 TO 25°C (68 TO
77°F). [SEE USP CONTROLLED ROOM TEMPERATURE.]
PROTECT FROM FREEZING. FOR I.V. USE.
USUAL DOSAGE: SEE INSERT.
STERILE, NONPYROGENIC. USE ONLY IF SOLUTION IS
CLEAR AND CONTAINER IS UNDAMAGED. MUST NOT BE
USED IN SERIES CONNECTIONS.

Rx ONLY

3
V
CONTAINS DEHP

IMP0000058

ICU Medical, Inc.
Lake Forest, Illinois, 60045 USA

icumedical

20 mEq POTASSIUM

1000 mL

NDC 0990-9257-39

POTASSIUM CHLORIDE

20 mEq

in 0.45% Sodium Chloride Injection, USP

EACH 100 mL CONTAINS POTASSIUM CHLORIDE 149 mg; SODIUM CHLORIDE 450 mg IN WATER FOR INJECTION. ELECTROLYTES PER 1000 mL: POTASSIUM 20 mEq; SODIUM 77 mEq; CHLORIDE; 97 mEq.
194 mOsmol/LITER (CALC.) pH 4.8 (3.5 to 6.5)

ADDITIVES MAY BE INCOMPATIBLE. CONSULT WITH PHARMACIST, IF AVAILABLE. WHEN INTRODUCING ADDITIVES, USE ASEPTIC TECHNIQUE, MIX THOROUGHLY AND DO NOT STORE.

SINGLE-DOSE CONTAINER. STORE AT 20 TO 25°C (68 TO 77°F). [SEE USP CONTROLLED ROOM TEMPERATURE.] PROTECT FROM FREEZING. FOR I.V. USE.
USUAL DOSAGE: SEE INSERT.
STERILE, NONPYROGENIC. USE ONLY IF SOLUTION IS CLEAR AND CONTAINER IS UNDAMAGED. MUST NOT BE USED IN SERIES CONNECTIONS.

Rx ONLY

3 V

LATEX

CONTAINS DEHP

IMP0000058
ICU Medical, Inc.
Lake Forest, Illinois, 60045 USA

icumedical

1 2 3 4 5 6 7 8 9

PRINCIPAL DISPLAY PANEL - 1000 mL Bag Overwrap

TO OPEN TEAR AT NOTCH

2
HDPE

DO NOT REMOVE FROM OVERWRAP UNTIL READY FOR USE. AFTER REMOVING THE OVERWRAP, CHECK FOR MINUTE LEAKS BY SQUEEZING CONTAINER FIRMLY. IF LEAKS ARE FOUND, DISCARD SOLUTION AS STERILITY MAY BE IMPAIRED. RECOMMENDED STORAGE: ROOM TEMPERATURE (25°C). AVOID EXCESSIVE HEAT. PROTECT FROM FREEZING. SEE INSERT.
98-4321-R14-3/98

POTASSIUM CHLORIDE IN SODIUM CHLORIDE

sodium chloride and potassium chloride injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0990-9257
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	4.5 g in 1000 mL
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152, CHLORIDE ION - UNII:Q32ZN48698)	POTASSIUM CHLORIDE	1.49 g in 1000 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0990-9257-39	12 in 1 CASE	03/01/2020	
1		1 in 1 POUCH		
1		1000 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078446	01/01/2020	

Labeler - ICU Medical Inc. (118380146)

Revised: 2/2023 ICU Medical Inc.