POTASSIUM CHLORIDE IN DEXTROSE AND SODIUM CHLORIDE

freeflex®

R_x only

Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection, USP

Flexible Plastic Container

DESCRIPTION

Intravenous solutions with potassium chloride (I.V. solutions with KCl) are sterile and nonpyrogenic solutions in water for injection. They are for administration by intravenous infusion only.

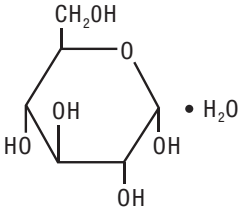
See table below for summary of content and characteristics of these solutions.

Table 1 Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection, USP		COMPOSITION (g/L)				Approx. Ionic Concentrations (mEq/L)				
mEq Potassium	Size (mL)	Dextrose, Hydrous	Sodium Chloride	Potassium Chloride	Calculated Osmolarity (mOsmol/L)	pH	Sodium (Na^+)	Potassium (K^+)	Chloride (Cl^-)	Approximate Kcal/L
10 mEq	500	50	4.5	1.49	447	4.2 (3.5 to 6.5)	77	20	97	170
10 mEq	1000	50	4.5	0.745	426	4.2 (3.5 to 6.5)	77	10	87	170
20 mEq	1000	50	4.5	1.49	447	4.2 (3.5 to 6.5)	77	20	97	170
30 mEq	1000	50	4.5	2.24	467	4.2 (3.5 to 6.5)	77	30	107	170
40 mEq	1000	50	4.5	2.98	487	4.2 (3.5 to 6.5)	77	40	117	170

May contain HCl for pH adjustment.
The solutions contain no bacteriostat, antimicrobial agent or added buffer and each is intended only for use as a single-dose injection. When smaller doses are required the unused portion should be discarded.

These solutions are parenteral fluid, nutrient and/or electrolyte replenishers.

Dextrose, USP is chemically designated D-glucose, monohydrate ($C_6H_{12}O_6 \bullet H_2O$), a hexose sugar freely soluble in water. It has the following structural formula:



Potassium Chloride, USP is chemically designated KCl, a white granular powder freely soluble in water.

Sodium Chloride, USP is chemically designated NaCl, a white crystalline powder freely soluble in water.

Water for Injection, USP is chemically designated H_2O.

The flexible plastic container is fabricated from a specially formulated non-plasticized, film containing polypropylene and thermoplastic elastomers (**free***flex*® bag). Water can permeate from inside the container into the overwrap but not in amounts sufficient to affect the solution significantly. Solutions in contact with the plastic container may leach out certain chemical components from the plastic in very small amounts; however, biological testing was supportive of the safety of the plastic container materials. Exposure to temperatures above 25°C/77°F during transport and storage will lead to minor losses in the moisture content. Higher temperatures lead to greater losses. It is unlikely that these minor losses will lead to clinically significant changes within the expiration period.

CLINICAL PHARMACOLOGY

When administered intravenously, these solutions provide a source of water and potassium chloride with carbohydrate (dextrose) and sodium chloride. See **HOW SUPPLIED** section for specific concentrations of these various solutions.

Solutions containing carbohydrate in the form of dextrose restore blood glucose levels and provide calories. Carbohydrate in the form of dextrose may aid in minimizing liver glycogen depletion and exerts a protein-sparing action. Dextrose injected parenterally undergoes oxidation to carbon dioxide and water.

Intravenous solutions containing potassium chloride are particularly intended to provide needed potassium cation (K^+). Potassium is the chief cation of body cells (160 mEq/liter of intracellular water). It is found in low concentration in plasma and extracellular fluids (3.5 to 5.0 mEq/liter in a healthy adult). Potassium plays an important role in electrolyte balance. Normally about 80 to 90% of the potassium intake is excreted in the urine; the remainder in the stools and to a small extent, in the perspiration. The kidney does not conserve potassium well so that during fasting or in patients on a potassium-free diet, potassium loss from the body continues resulting in potassium depletion. A deficiency of either potassium or chloride will lead to a deficit of the other.

Sodium chloride in water dissociates to provide sodium (Na^+) and chloride (Cl^-) ions. Sodium (Na^+) is the principal cation of the extracellular fluid and plays a large part in the therapy of fluid and electrolyte disturbances. Chloride (Cl^-) has an integral role in buffering action when oxygen and carbon dioxide exchange occurs in the red blood cells. The distribution and excretion of sodium (Na^+) and chloride (Cl^-) are largely under the control of the kidney which maintains a balance between intake and output.

Water is an essential constituent of all body tissues and accounts for approximately 70% of total body weight. Average normal adult daily requirement ranges from two to three liters (1.0 to 1.5 liters each for insensible water loss by perspiration and urine production).

Water balance is maintained by various regulatory mechanisms. Water distribution depends primarily on the concentration of electrolytes in the body compartments and sodium (Na^+) plays a major role in maintaining physiologic equilibrium.

INDICATIONS AND USAGE

These solutions are indicated in patients requiring parenteral administration of potassium chloride with minimal carbohydrate calories and sodium chloride.

CONTRAINDICATIONS

Solutions containing potassium chloride are contraindicated in diseases where high potassium levels may be encountered.

WARNINGS

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.

To avoid potassium intoxication, do not infuse these solutions rapidly. In patients with severe renal insufficiency or adrenal insufficiency, administration of potassium chloride may cause potassium intoxication.

Solutions containing sodium ions 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.

In patients with diminished renal function, administration of solutions containing sodium or potassium ions may result in sodium or potassium retention.

The intravenous administration of these solutions 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 concentration of administered parenteral solutions. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of such solutions.

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.

Solutions containing dextrose should be used with caution in patients with known subclinical or overt diabetes mellitus.

Caution must be exercised in the administration of parenteral fluids, especially those containing sodium ions, to patients receiving corticosteroids or corticotropin.

Potassium replacement therapy should be guided primarily by serial electrocardiograms. Plasma potassium levels are not necessarily indicative of tissue potassium levels.

High plasma concentrations of potassium may cause death through cardiac depression, arrhythmias or arrest.

Potassium-containing solutions should be used with caution in the presence of cardiac disease, particularly in digitalized patients or in the presence of renal disease.

Care should be exercised to insure that the needle (or catheter) is well within the lumen of the vein and that extravasation does not occur.

Do not administer unless solution is clear and container is undamaged. Discard unused portion.

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Studies with solutions from flexible plastic containers have not been performed to evaluate carcinogenic potential, mutagenic potential or effects on fertility.

Pregnancy Animal reproduction studies have not been conducted with dextrose, potassium chloride or sodium chloride. It is also not known whether dextrose, potassium chloride or sodium chloride can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Dextrose, potassium chloride or sodium chloride should be given to a pregnant woman only if clearly needed.

Nursing Mothers:

Caution should be exercised when solutions from flexible plastic containers are administered to a nursing mother.

Pediatric Use:

The safety and effectiveness in the pediatric population are based on the similarity of the clinical conditions of the pediatric and adult populations. In neonates or very small infants the volume of fluid may affect fluid and electrolyte balance.

Frequent monitoring of serum glucose concentrations is required when dextrose is prescribed to pediatric patients, particularly neonates and low birth weight infants.

In very low birth weight infants, excessive or rapid administration of dextrose injection may result in increased serum osmolality and possible intracerebral hemorrhage.

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. Sodium and 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

Reactions which may occur because of the solutions or 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.

Nausea, vomiting, abdominal pain and diarrhea have been reported with potassium therapy. 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.

Potassium-containing solutions are intrinsically irritating to tissues. Therefore, extreme care should be taken to avoid perivascular infiltration. Local tissue necrosis and subsequent sloughing may result if extravasation occurs. Chemical phlebitis and venospasm have also been reported.

Should perivascular infiltration occur, I.V. administration at that site should be discontinued at once. Local infiltration of the affected area with procaine hydrochloride, 1%, to which hyaluronidase may be added, will often reduce venospasm and dilute the potassium remaining in the tissues locally. Local application of heat may also be helpful.

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC at 1-800-551-7176 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

OVERDOSAGE

In the event of potassium overdosage, discontinue the infusion immediately and institute intensive corrective therapy to reduce serum potassium levels. See ***WARNINGS*** and ***PRECAUTIONS***.

DOSAGE AND ADMINISTRATION

These solutions should be administered only by intravenous infusion and as directed by the physician. The dose and rate of injection are dependent upon the age, weight and clinical condition of the patient. If the serum potassium level is greater than 2.5 mEq/liter, potassium should be given at a rate not to exceed 10 mEq/hour in a concentration less than 30 mEq/liter. Somewhat faster rates and greater concentrations (usually up to 40 mEq/liter) of potassium may be indicated in patients with more severe potassium deficiency. The total 24- hour dose should not generally exceed 200 mEq of potassium.

As reported in the literature, the dosage and constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low birth weight infants, because of the increased risk of hyperglycemia/hypoglycemia.

Drug Interactions

Additives may be incompatible. Consult with pharmacist, if available. When introducing additives, use aseptic technique, mix thoroughly and do not store.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. See ***PRECAUTIONS***.

HOW SUPPLIED

Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection, USP is supplied in single-dose **free***flex*® plastic containers as follows:

Product Code	Unit of Use	Strength	Unit of Sale
245075	NDC 65219-150-00 One 500 mL **free***flex*® bag	10 mEq Potassium Chloride	NDC 65219-150-75 Package of 20 **free***flex*® bags
224210	NDC 65219-142-02 One 1000 mL **free***flex*® bag	10 mEq Potassium Chloride	NDC 65219-142-10 Package of 10 **free***flex*® bags
244410	NDC 65219-144-04 One 1000 mL **free***flex*® bag	20 mEq Potassium Chloride	NDC 65219-144-10 Package of 10 **free***flex*® bags
244610	NDC 65219-146-06 One 1000 mL **free***flex*® bag	30 mEq Potassium Chloride	NDC 65219-146-10 Package of 10 **free***flex*® bags
244810	NDC 65219-148-08 One 1000 mL **free***flex*® bag	40 mEq Potassium Chloride	NDC 65219-148-10 Package of 10 **free***flex*® bags

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

The container closure is not made with natural rubber latex. Non-PVC, Non-DEHP, Sterile.

INSTRUCTIONS FOR USE

Check flexible container solution composition, lot number, and expiry date.
Do not remove solution container from its overwrap until immediately before use. Use sterile equipment and aseptic technique.

Flexible Plastic Container (**free***flex*® bag)

To Open

1. Turn solution container over so that the text is face down. Using the pre-cut corner tabs, peel open the overwrap and remove solution container.
2. Check the solution container for leaks by squeezing firmly. If leaks are found, or if the seal is not intact, discard the solution.
3. Do not use if the solution is cloudy or a precipitate is present.

To Add Medication

1. Identify WHITE Additive Port with arrow pointing toward container.
2. Immediately before injecting additives, break off WHITE Additive Port Cap with the arrow pointing toward container.
3. Hold base of WHITE Additive Port horizontally.
4. Insert needle horizontally through the center of WHITE Additive Port's septum and inject additives.
5. Mix container contents thoroughly.

Preparation for Administration

1. Immediately before inserting the infusion set, break off BLUE Infusion Port Cap with the arrow pointing away from container.
2. Use a non-vented infusion set or close the air-inlet on a vented set.
3. Close the roller clamp of the infusion set.
4. Hold the base of BLUE Infusion Port.
5. Insert spike through BLUE Infusion Port by rotating wrist slightly until the spike is inserted. **NOTE:** See full directions accompanying administration set.

WARNING: Do not use flexible container in series connections.

Manufactured for:

FRESENIUS KABI
Lake Zurich, Illinois 60047

Made in Norway

451750
www.fresenius-kabi.com/us

Issued: May 2022

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01-59-16-009