Potassium Chloride in Lactated Ringer’s and 5% Dextrose Injection, USP in Plastic Container

VIAFLEX Plus Container

Description
Potassium Chloride in Lactated Ringer’s and 5% Dextrose Injection, USP is a sterile, nonpyrogenic solution for fluid and electrolyte replenishment and caloric supply in a single dose container for intravenous administration. It contains no Epstein-Barr virus particles. Composition, osmolality, pH, ionic concentration and caloric content are shown below:

<table>
<thead>
<tr>
<th>Component</th>
<th>Concentration (g/L)</th>
<th>Chilled</th>
<th>Lactated</th>
<th>pH</th>
<th>Caloric Content (kcal/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Chloride, USP (NaCl)</td>
<td>3.0 (3.5 to 4.0)</td>
<td>900</td>
<td>40</td>
<td>3.2</td>
<td>150</td>
</tr>
<tr>
<td>Dextrose Hydrous, USP</td>
<td>5.0 (5.5 to 6.5)</td>
<td>100</td>
<td>40</td>
<td>3.9</td>
<td>140</td>
</tr>
</tbody>
</table>

** The chemical structure for Dextrose Hydrous, USP is shown below:

VIAFLEX Plus plastic container is fabricated from a specially formulated polyvinyl chloride (PL 146 Plastic). VIAFLEX Plus on the container indicates the presence of a drug additive in a drug vehicle. The VIAFLEX Plus plastic container system utilizes the same container as the VIAFLEX plastic container system. The amount of water that can permeate from inside the container into the environment 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, e.g., di-2-ethylhexyl phthalate (DEHP), up to 5 parts per million. However, the safety of the plastic has been confirmed in tests in animals according to USP biological tests for plastic containers as well as by tissue culture toxicity studies.

Clinical Pharmacology
Potassium Chloride in Lactated Ringer’s and 5% Dextrose Injection, USP have value as a source of water, electrolytes, and calories. It is capable of inducing diuresis depending on the clinical condition of the patient. Potassium Chloride in Lactated Ringer’s and 5% Dextrose Injection, USP produce a metabolic alkalinizing effect. Lactate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations.

Indications and Usage
Potassium Chloride in Lactated Ringer’s and 5% Dextrose Injection, USP are indicated as a source of water, electrolytes, and calories as an alkalinizing agent.

Contraindications
Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.

Warnings
Potassium Chloride in Lactated Ringer’s and 5% Dextrose Injection, USP should be used with great care in patients with overt or subclinical diabetes mellitus.

Potassium Chloride in Lactated Ringer’s and 5% Dextrose Injection, USP should be used with great care in patients with overt or subclinical diabetes mellitus. Potassium Chloride in Lactated Ringer’s and 5% Dextrose Injection, USP should be used with great care in patients with severe renal insufficiency, as in clinical states in which there exists edema with sodium retention.

Potassium Chloride in Lactated Ringer’s and 5% Dextrose Injection, USP should be used with great care in patients with hyperkalemia, severe renal failure, and in conditions in which potassium retention is present.

Potassium Chloride in Lactated Ringer’s and 5% Dextrose Injection, USP should be used with great care in patients with metabolic or respiratory alkalosis.

In very low birth weight infants, excessive or rapid administration of dextrose injection may result in increased serum osmolality and possible intracerebral hemorrhage. The administration of lactate ions should be done with great care in those conditions in which there is an increased level or an impaired utilization of these ions, such as severe hepatic insufficiency.

Potassium Chloride in Lactated Ringer’s and 5% Dextrose Injection, USP should not be administered simultaneously with blood through the same administration set because of the likelihood of coagulation.

The intravenous administration of Potassium Chloride in Lactated Ringer’s and 5% Dextrose 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 Lactated Ringer’s and 5% Dextrose Injection, USP may result in sodium or potassium retention.

In patients with diminished renal function, administration of Potassium Chloride in Lactated Ringer’s and 5% Dextrose Injection, USP should not be administered simultaneously with blood through the same administration set because of the likelihood of coagulation.

Potassium Chloride in Lactated Ringer’s and 5% Dextrose Injection, USP should not be used in the treatment of lactic acidosis.

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.

Potassium Chloride in Lactated Ringer’s and 5% Dextrose Injection, USP should be used with caution. Excess administration may result in metabolic alkalosis.

Caution must be exercised in the administration of Potassium Chloride in Lactated Ringer’s and 5% Dextrose Injection, USP to patients receiving corticosteroids or corticotropin.

Potassium Chloride in Lactated Ringer’s and 5% Dextrose Injection, USP should be used with caution in patients with overt or subclinical diabetes mellitus.
Pregnancy: Teratogenic Effects

Pregnancy Category C. Animal reproduction studies have not been conducted with Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP. It is also not known whether Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Potassium Chloride in Lactated Ringer's and 5% Dextrose Injection, USP should be given to a pregnant woman only if clearly needed.

Pediatric Use: Safety and effectiveness of Potassium Chloride in Lactated Ringer's and 5% Dextrose 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. Dextrose is safe and effective for the stated indications in pediatric patients (see Indications and Usage). As reported in the literature, the dosage selection 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. Frequent monitoring of serum glucose concentrations is required when dextrose is prescribed in pediatric patients, particularly neonates and low birth weight infants.

Geriatric Use: Clinical studies of Potassium Chloride in Lactated Ringer's and 5% Dextrose 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 geriatric patients between the elderly and younger patients. In general, dosage 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 drug therapy. For patients receiving potassium supplement at greater than maintenance rates, frequent monitoring of serum potassium levels and serial EKGs are recommended. 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.

Carcinogenesis, mutagenesis, impairment of fertility

Studies with Potassium Chloride in Lactated Ringer's and 5% Dextrose 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 Lactated Ringer's and 5% Dextrose Injection, USP is administered to a nursing mother.

Adverse Reactions

Reactions which may occur because of the solution or the technique of administration include sterile response, infusion at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation, and hypokalemia. 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 a final filter is recommended during administration of all parenteral solutions, where possible. All injections in VIAFLEX Plus plastic containers are intended for intravenous administration using sterile equipment.

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Deerfield, IL 60015 USA
Printed in USA

*For Bar Code Position Only

2B2244 1000 0338-0815-04 40 mEq/L Potassium

To add medication during solution administration

1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture reusable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Gag clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture reusable medication port and inject.
4. Remove container from IV pole and turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.
6. Mix solution and medication thoroughly.
7. Return container to in use position and continue administration.