Potassium Chloride in 5% Dextrose Injection, USP in Plastic Container
VIAFLEX Plus Container

Description
Potassium Chloride in 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 antimicrobial agents. Composition, osmolarity, pH, cationic concentration and caloric content are shown in Table 1.

Table 1

<table>
<thead>
<tr>
<th>Size (mL)</th>
<th>Composition (g/L)</th>
<th>Ionic Concentration (mEq/L)</th>
<th>pH</th>
<th>Potassium</th>
<th>Chloride</th>
<th>Dextrose</th>
<th>Caloric Content (kcal/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 mEq</td>
<td>1000</td>
<td>50</td>
<td>0.75</td>
<td>3.5 to 6.5</td>
<td>4.5</td>
<td>170</td>
<td>3.5 to 6.5</td>
</tr>
<tr>
<td>100 mEq</td>
<td>1000</td>
<td>50</td>
<td>1.5</td>
<td>3.5 to 6.5</td>
<td>4.5</td>
<td>170</td>
<td>3.5 to 6.5</td>
</tr>
<tr>
<td>200 mEq</td>
<td>1000</td>
<td>50</td>
<td>3.0</td>
<td>3.5 to 6.5</td>
<td>4.5</td>
<td>170</td>
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<td>170</td>
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</tr>
</tbody>
</table>

**Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L.**

Potassium Chloride in 5% Dextrose Injection, USP is a source of water, electrolytes, and calories. It is capable of inducing diuresis depending on the ionic concentration of the injection.

Warnings
Potassium Chloride in 5% Dextrose 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.

Intravenous injections containing carbohydrates with low electrolyte concentration should not be administered simultaneously with blood through the same administration set because of the possibility of pseudoagglutination or hemolysis. The bag label for these injections bears the statement: Do not administer simultaneously with blood.

Indications and Usage
Potassium Chloride in 5% Dextrose Injection, USP is a source of electrolytes and calories. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

Potassium Chloride in 5% Dextrose Injection, USP may result in potassium retention.

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

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 5% Dextrose Injection, USP should be used with caution in patients with overt or subclinical diabetes mellitus.

Potassium Chloride in 5% Dextrose Injection, USP may result in potassium retention.

In patients with diminished renal function, administration of Potassium Chloride in 5% Dextrose Injection, USP may result in increased serum osmolality and possible intracerebral hemorrhage.

Pediatric Use:
Safety and effectiveness of Potassium Chloride in 5% Dextrose Injection, USP have not been established in pediatric patients. 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.

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Potassium salts should never be administered by IV push.

**Contraindications**
Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.
Geriatric Use
Clinical studies of Potassium Chloride in 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 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.

Carcinogenesis, mutagenesis, impairment of fertility
Studies with Potassium Chloride in 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 5% Dextrose Injection, USP is administered to a nursing mother.

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 tachyuria, 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 a final filter is recommended during administration of all parenteral solutions, where possible.

All injections in VIAFLEX Plus plastic containers are intended for intravenous solutions, where possible.

Use of a final filter is recommended during administration of all parenteral 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.

To add medication during solution administration
1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Mix solution and medication thoroughly. For high density medication such as potassium chloride; square ports while ports are upright and mix thoroughly.

To add medication during solution administration
1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or 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.

Dosage Administration
To Add Medication
1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
3. Mix solution and medication thoroughly. For high density medication such as potassium chloride; square ports while ports are upright and mix thoroughly.

Preparation for Administration
1. Suspend container from eyelet support.
2. Remove protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To add medication before solution administration
1. Prepare medication site.
2. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
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How Supplied
Potassium Chloride in 5% Dextrose Injection, USP in VIAFLEX Plus plastic container is available as follows:

<table>
<thead>
<tr>
<th>Code</th>
<th>Size (mL)</th>
<th>NDC</th>
<th>Product Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>2B1124</td>
<td>1000</td>
<td>0338-0681-04</td>
<td>10 mEq Potassium Chloride in 5% Dextrose Injection, USP</td>
</tr>
<tr>
<td>2B1134</td>
<td>1000</td>
<td>0338-0683-04</td>
<td>20 mEq Potassium Chloride in 5% Dextrose Injection, USP</td>
</tr>
<tr>
<td>2B1174</td>
<td>1000</td>
<td>0338-0685-04</td>
<td>30 mEq Potassium Chloride in 5% Dextrose Injection, USP</td>
</tr>
<tr>
<td>2B1264</td>
<td>1000</td>
<td>0338-0687-04</td>
<td>40 mEq Potassium Chloride in 5% Dextrose Injection, USP</td>
</tr>
<tr>
<td>2B1263</td>
<td>500</td>
<td>0338-0687-03</td>
<td>20 mEq Potassium Chloride in 5% Dextrose Injection, USP</td>
</tr>
</tbody>
</table>

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (59°F) — brief exposure up to 40°C does not adversely affect the product.

Directions for Use of VIAFLEX Plus Plastic Container
Warning: Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before administration of the fluid from the secondary container is completed.

To Open
Tear overwrap down side at slit and remove solution container. 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 sterilant may be impaired. If supplemental medication is desired, follow designated levels below.

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1. Suspend container from eyepet support.
2. Remove protector from outlet port at bottom of container.
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