

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

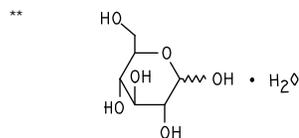
DESCRIPTION

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, ionic concentration and caloric content are shown in Table 1.

Table 1

| Potassium Chloride in 5% Dextrose Injection, USP | Size (mL) | Composition (g/L) | | *Osmolarity (mOsmol/L) (calc.) | pH | Ionic Concentration (mEq/L) | | Caloric Content (kcal/L) |
|--|-----------|-------------------------|-------------------------------|-----------------------------------|---------------------|-----------------------------|----------|--------------------------|
| | | **Dextrose Hydrous, USP | Potassium Chloride, USP (KCl) | | | Potassium | Chloride | |
| mEq Potassium | | | | | | | | |
| 20 mEq | 1000 | 50 | 1.5 | 293 | 4.5 (3.5 to 6.5) | 20 | 20 | 170 |

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



D-Glucose monohydrate

Dextrose is derived from corn.

This 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 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, 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 5% Dextrose Injection, USP is a source of water, electrolytes and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

INDICATIONS AND USAGE

Potassium Chloride in 5% Dextrose Injection, USP is indicated as a source of water, electrolytes, and calories.

CONTRAINDICATIONS

Potassium Chloride in 5% Dextrose Injection, USP must not be used in patients with:

- known hypersensitivity to the product,
- clinically significant hyperkalemia (see **WARNINGS**).

WARNINGS

Hypersensitivity

Hypersensitivity/infusion reactions, including anaphylaxis and chills may occur. Stop the infusion immediately if signs or symptoms of suspected hypersensitivity/infusion reactions develop. Appropriate therapeutic counter measures must be instituted as clinically indicated.

Hyperkalemia

Administer Potassium Chloride in 5% Dextrose Injection, USP with caution, if at all, in patients 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 digitalis), potassium-aggravated skeletal muscle channelopathies (e.g., hyperkalemic periodic paralysis, paramyotonia congenital, and potassium-aggravated myotonia/paramyotonia). Administer Potassium Chloride in 5% Dextrose Injection, USP with caution to patients 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) and patients treated concurrently or recently with agents or products that can cause hyperkalemia or increase the risk of hyperkalemia (see **DRUG INTERACTIONS**). Administer Potassium Chloride in 5% Dextrose Injection, USP with caution in other groups of patients with cardiac arrhythmia. Arrhythmias can develop at any time during hyperkalemia.

Frequently, mild or moderate hyperkalemia is asymptomatic and may be manifested only by increased serum potassium concentrations and, possibly, characteristic ECG changes.

Risk of Severe Renal Impairment

Administer Potassium Chloride in 5% Dextrose Injection, USP with particular caution, to patients with or at risk of severe renal impairment. In such patients, administration of Potassium Chloride in 5% Dextrose Injection, USP may result in or predispose to potassium retention, hyperkalemia and/or fluid overload.

Hyperglycemia and Hyperosmolar Hyperglycemic State

The use of dextrose infusions in patients with diabetes mellitus or impaired glucose tolerance may worsen hyperglycemia. Administration of dextrose at a rate exceeding the patient's utilization rate may lead to hyperglycemia, coma, and death. Patients with underlying CNS disease and/or renal impairment who receive dextrose infusions, may be at greater risk of developing hyperosmolar hyperglycemic state.

Administer intravenous dextrose with caution in patients with, for example:

- impaired glucose tolerance (such as in diabetes mellitus, renal impairment, or in the presence of sepsis, trauma, or shock),
- thiamine deficiency, due to the risk of severe lactic acidosis as a result of impaired oxidative metabolism of pyruvate,
- water and electrolyte disturbances that could be aggravated by increased glucose and/or free water load.

Other groups of patients in whom Potassium Chloride in 5% Dextrose Injection, USP should be used with caution include:

- Patients with ischemic stroke. Hyperglycemia has been implicated in increasing cerebral ischemic brain damage and impairing recovery after acute ischemic strokes.
- Patients with severe traumatic brain injury (in particular during the first 24 hours following the trauma). Early hyperglycemia has been associated with poor outcomes in patients with severe traumatic brain injury.
- Neonates. In very low birth weight infants, excessive or rapid administration of dextrose injection may result in increased serum osmolality and possible intracerebral hemorrhage. For pediatric glycemia-related issues, see PRECAUTIONS, Pediatric Use.

Monitor blood glucose levels and treat hyperglycemia to maintain optimum levels while administering Potassium Chloride in 5% Dextrose Injection, USP. Insulin may be administered or adjusted to maintain optimal blood glucose levels during Dextrose Injection administration.

Electrolyte Imbalance and Fluid Overload

Electrolyte deficits, particularly in serum potassium and phosphate, may occur during prolonged use of dextrose solutions.

Depending on the volume and rate of infusion, the intravenous administration of dextrose 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 concentrations in the administered solution. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations in the solution. Monitor blood electrolyte levels, acid-base balance, correct fluid and electrolyte imbalances, and administer essential vitamins and minerals as needed. Monitor daily fluid balance. Hyponatremia and a decrease in extracellular sodium concentrations related to hyperglycemia causing a transcellular shift of water.

Particular caution must be exercised in patients at increased risk of and from water and electrolyte disturbances. Infusion of Potassium Chloride in 5% Dextrose Injection, USP corresponds to the increasing body's load of free water, possibly leading to hypoosmotic hyponatremia.

Hyponatremia

The use of Potassium Chloride in 5% Dextrose Injection, USP may result in hyponatremia. Close clinical monitoring may be warranted.

Hyponatremia can lead to headache, nausea, seizures, lethargy, coma, cerebral edema, and death. Acute symptomatic hyponatremic encephalopathy is considered a medical emergency.

The risk for developing hypoosmotic hyponatremia is increased for example, in pediatric patients in elderly patients, in women, postoperatively, in persons with psychogenic polydipsia.

The risk for developing encephalopathy as a complication of hypoosmotic hyponatremia is increased, for example; in pediatric patients (≤ 16 years of age), in women (in particular, premenopausal women), in patients with hypoxemia, and in patients with underlying central nervous system disease, see PRECAUTIONS, Pediatric Use and Geriatric Use.

Hypokalemia

The infusion of solutions with Potassium Chloride in 5% Dextrose Injection, USP may result in hypokalemia. Hypokalemia can lead to arrhythmias, muscle weakness, paralysis, heart block, and rhabdomyolysis.

Administer Potassium Chloride in 5% Dextrose Injection, USP with particular caution, warranting close clinical monitoring, for example: in persons with metabolic alkalosis, in persons with thyrotoxic or hypokalemic periodic paralysis, in persons with increased gastrointestinal losses (e.g., diarrhea, vomiting), in persons on prolonged low potassium diet (e.g.,

undernourished or cachectic patients), in persons with primary hyperaldosteronism, in patients treated with medications that increase the risk of hypokalemia (e.g. hydrochlorothiazide, loop diuretics, beta-2 agonists, or insulin).

Refeeding syndrome

Refeeding severely undernourished patients may result in the refeeding syndrome that is characterized by the shift of potassium, phosphorus, and magnesium intracellularly as the patient becomes anabolic. Thiamine deficiency and fluid retention may also develop. Careful monitoring and slowly increasing nutrient intake while avoiding overfeeding can prevent these complications.

PRECAUTIONS

General

Potassium Chloride in 5% Dextrose Injection, USP should not be administered simultaneously with blood through the same administration set because of the possibility of pseudoagglutination or hemolysis.

Do not connect flexible plastic containers in series in order to avoid air embolism due to possible residual air contained in the primary container.

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.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.

Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

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

Drug Interactions

Both the glycemic effects of Potassium Chloride in 5% Dextrose Injection, USP and its effects on water and electrolyte balance should be taken into account when using Potassium Chloride in 5% Dextrose Injection, USP in patients treated with other substances that affect glycemic control, or fluid and/or electrolyte balance.

Potassium Chloride in 5% Dextrose Injection, USP should be used with caution in patients treated concurrently or recently with agents or products that can cause hyperkalemia or increase the risk of hyperkalemia, such as potassium-sparing diuretics (e.g., amiloride, spironolactone, triamterene), corticosteroids, ACE inhibitors, ciclosporin, tacrolimus and drugs that contain potassium.

Administration of potassium in patients treated with such agents is associated with an increased risk of severe and potentially fatal hyperkalemia, in particular in the presence of other risk factors for hyperkalemia.

Potassium Chloride in 5% Dextrose Injection, USP should be used with caution in patients treated concurrently or recently with medications that may increase the risk of hyponatremia, or sodium and fluid retention, such as corticosteroids.

Pregnancy

There are no adequate and well controlled studies with Potassium Chloride in 5% Dextrose Injection, USP in pregnant women and animal reproduction studies have not been conducted with this drug. Therefore, it is not known whether Potassium Chloride in 5% Dextrose Injection, USP can cause fetal harm when administered to a pregnant woman. Potassium Chloride in 5% Dextrose Injection, USP should be given during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Labor and Delivery

Intrapartum maternal intravenous infusion of glucose-containing solutions may produce maternal hyperglycemia with subsequent fetal hyperglycemia and fetal metabolic acidosis as well as rebound neonatal hypoglycemia due to fetal insulin production (see Pediatric Use).

Consider the potential risks and benefits for each specific patient before administering Potassium Chloride in 5% Dextrose Injection, USP.

Nursing Mothers

It is not known whether this drug is present in human milk. Because many drugs are present in human milk, caution should be exercised when Potassium Chloride in 5% Dextrose Injection, USP is administered to a nursing woman.

Pediatric Use

The use of Potassium Chloride in 5% Dextrose Injection, USP in pediatric patients is based on clinical practice. (See **DOSAGE AND ADMINISTRATION**)

Neonates, especially those born premature and with low birth weight are at increased risk of developing hypo – or hyperglycemia and therefore need close monitoring during treatment with

intravenous glucose infusions to ensure adequate glycemic control in order to avoid potential long term adverse effects.

Hypoglycemia in the newborn can cause prolonged seizures, coma and brain damage.

Hyperglycemia has been associated with intraventricular hemorrhage, late onset bacterial and fungal infection, retinopathy of prematurity, necrotizing enterocolitis, prolonged length of hospital stay, and death.

Plasma electrolyte concentrations should be closely monitored in the pediatric population as this population may have impaired ability to regulate fluids and electrolytes. In very low birth weight infants, excessive or rapid administration of dextrose solutions may result in increased serum osmolality and possible intracerebral hemorrhage.

Children (including neonates and older children) are at increased risk of developing hyponatremia as well as for developing hyponatremic encephalopathy. The infusion of hypotonic fluids together with the non-osmotic secretion of ADH may result in hyponatremia.

Hyponatremia can lead to headache, nausea, seizures, lethargy, coma, cerebral edema and death; therefore, acute symptomatic hyponatremic encephalopathy is considered a medical emergency.

Rapid correction of hyponatremia is potentially dangerous (risk of serious neurologic complications). Dosage, rate, and duration of administration should be determined by a physician experienced in pediatric intravenous fluid therapy.

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. Elderly patients are at increased risk of developing hyponatremia as well as for developing hyponatremic encephalopathy (see WARNINGS).

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. 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.

ADVERSE REACTIONS

The following adverse reactions associated with the use of Potassium Chloride in 5% Dextrose Injection, USP were identified in clinical trials or postmarketing reports. Because these 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.

Hypersensitivity reactions: including anaphylaxis and chills.

General disorders and administration site conditions: Infusion site rash, Infusion site pain.

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.

Other adverse reactions reported with potassium chloride and dextrose injections/infusions include:

Metabolism and nutrition disorders: Hyperkalemia, hypokalemia.

General disorders and administration disorders and administration site conditions: Infusion site reactions, including Infusion site vesicles, Infusion site pruritus, Infusion site phlebitis, Chills, Pyrexia

Cardiac disorders: Cardiac arrest, as a manifestation of hyperkalemia.

OVERDOSAGE

Excess administration of Potassium Chloride in 5% Dextrose Injection, USP can cause:

- Hyperkalemia (See **WARNINGS** and **ADVERSE REACTIONS**). 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 levels. Manifestations of hyperkalemia may include:
 - disturbances in cardiac conduction and arrhythmias, including bradycardia, heart block, asystole, ventricular tachycardia, ventricular fibrillation, and ECG changes (peaking of T waves, loss of P waves, and QRS widening). However, the correlation between potassium levels and ECG changes is not precise, and whether or at which potassium level certain ECG signs develop depends on factors such as patient sensitivity, the presence of other electrolyte disorders and the rapidity of the development of hyperkalemia.
 - hypotension,

- muscle weakness up to and including muscular and respiratory paralysis, paresthesia of extremities,
- gastrointestinal symptoms (ileus, nausea, vomiting, abdominal pain).

An increased infusion rate of dextrose solution can cause hyperglycemia, hyperosmolality, and adverse effects on water and electrolyte balance.

Severe hyperglycemia and severe dilutional hyponatremia, and their complications, can be fatal. Discontinue infusion and institute appropriate corrective measures in the event of overhydration or solute overload during therapy, with particular attention to CNS, respiratory and cardiovascular systems (see **WARNINGS**).

- When assessing an overdose, any additives in the solution must also be considered.
- Clinically significant overdose of Potassium Chloride in 5% Dextrose Injection, USP may, therefore, constitute a medical emergency.
- Interventions include discontinuation of Potassium Chloride in 5% Dextrose Injection, USP administration, dose reduction, administration of insulin and other measures as indicated for the specific clinical constellation.

DOSAGE AND ADMINISTRATION

Potassium Chloride in 5% Dextrose Injection, USP is for intravenous infusion.

Potassium Chloride in 5% Dextrose injection, USP should not be administered by intravenous push.

Potassium Chloride in 5% Dextrose Injection, USP has an osmolarity of 293 mOsmol/L (calc).

The choice of specific potassium chloride and dextrose dosage, volume, rate and duration of administration depends on the age, weight and clinical condition of the patient, concomitant therapy, and administration should be determined by a physician.

For patients with electrolyte and glucose abnormalities and for pediatric patients, consult a physician experienced in intravenous fluid therapy.

A gradual increase of flow rate should be considered when starting administration of dextrose-containing products.

Electrolyte supplementation may be indicated according to the clinical needs of the patient.

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.

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

All injections in VIAFLEX Plus plastic containers are intended for intravenous administration using sterile equipment.

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 to pediatric patients, particularly neonates and low birth weight infants. The infusion rate and volume depends on the age, weight, clinical and metabolic conditions of the patient, concomitant therapy and should be determined by the consulting physician experienced in pediatric intravenous fluid therapy.

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. When introducing additives to Potassium Chloride in 5% Dextrose Injection, USP, the instructions for use of the medication to be added and other relevant literature must be consulted. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

HOW SUPPLIED

Potassium Chloride in 5% Dextrose Injection, USP in VIAFLEX Plus plastic container is available as follows:

| Code | Size (mL) | NDC | Product Name |
|--------|-----------|--------------|---|
| 2B1134 | 1000 | 0338-0683-04 | 20 mEq Potassium Chloride in 5% Dextrose Injection, USP |

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C); brief exposure up to 40°C does not adversely affect the product.

DIRECTIONS FOR USE OF VIAFLEX PLUS PLASTIC CONTAINER

For information on risk of air embolism – see **PRECAUTIONS**.

To Open

Tear overwrap down side at slit and remove solution container. 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.

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

- Additives known or determined to be incompatible should not be used.
- Before adding a substance or medication, verify that it is soluble and/or stable in Potassium Chloride in 5% Dextrose Injection, USP and that the pH range of Potassium Chloride in 5% Dextrose Injection, USP is appropriate.
- The instructions for use of the medication to be added and other relevant literature must be consulted.

- When introducing additives to Potassium Chloride in 5% Dextrose Injection, USP aseptic technique must be used.
- After addition, if there is a color change and/or the appearance of precipitates, insoluble complexes or crystals, do not use.
- Mix the solution thoroughly when additives have been introduced.
- Do not store solutions containing additives.
- Single – dose container.
- Discard any unused portion.

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.
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. 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.

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