

PRESCRIBING INFORMATION

**Potassium Chloride in Dextrose and Sodium Chloride  
Injection, USP**

**Solution for Infusion**  
Solutions Affecting the Electrolyte Balance

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## **Potassium Chloride in Dextrose and Sodium Chloride Injection, USP**

### **In VIAFLEX Plastic Container**

#### **Description**

Potassium Chloride in Dextrose and Sodium Chloride 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**.

The VIAFLEX 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, 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 Dextrose and Sodium Chloride Injection, USP has value as 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 Dextrose and Sodium Chloride Injection, USP is indicated as a source of water, electrolytes and calories. Dextrose-containing solutions may also be indicated in clinical conditions where enteral nutritional supply is or is expected to be insufficient or impossible.

## **Contraindications**

Potassium Chloride in Dextrose and Sodium Chloride Injection, USP must not be used in patients with:

- Clinically significant hyperglycemia
- Clinically significant hyperkalemia
- Patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container.
- Known allergy to corn or corn products since dextrose in the product is purified from corn.

For a complete listing, see the Description section of the Prescribing Information.

## **Special Warnings and Precautions for Use**

### **Warnings**

Potassium Chloride in Dextrose and Sodium Chloride Injection, USP 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.

Potassium Chloride in Dextrose and Sodium Chloride 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.

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 intravenous administration of Potassium Chloride in Dextrose and Sodium Chloride 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 Dextrose and Sodium Chloride Injection, USP may result in sodium or potassium retention.

### **Hypersensitivity Reactions**

Hypersensitivity/infusion reactions, including anaphylaxis, have been reported with Potassium Chloride in Dextrose and Sodium Chloride Injection, USP (see Adverse Reactions). Stop the infusion immediately if signs or symptoms of hypersensitivity/infusion reactions develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated. Solutions containing dextrose should be used with caution in patients with known allergy to corn or corn products.

### **Hyponatremia - Potassium Chloride (10mmol/L- 40mmol/L) in 2.5-5% Dextrose and 0.18-0.45% Sodium Chloride Injection, USP**

Glucose intravenous infusions are usually isotonic solutions. In the body, however, glucose containing fluids can become extremely physiologically hypotonic due to rapid glucose metabolism.

Monitoring of serum sodium is particularly important for hypotonic fluids. See Table 1 for information on the products' osmolarity.

Depending on the tonicity of the solution, the volume and rate of infusion, and depending on a patient's underlying clinical condition and capability to metabolize glucose, intravenous administration of glucose can cause electrolyte disturbances, most importantly hypo- or hyperosmotic hyponatremia.

High volume infusion must be used under specific monitoring in patients with cardiac or pulmonary failure, and in patients with non-osmotic vasopressin release (including syndrome of inappropriate antidiuretic hormone secretion (SIADH)), due to risk of hospital-acquired hyponatremia.

Acute hyponatremia can lead to acute hyponatremic encephalopathy (brain edema) 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 for hyponatremia is increased, for example, in children, in elderly patients, in women, postoperatively, in persons with psychogenic polydipsia, and in patients treated with medications that increase the risk of hyponatremia (See Interactions with Other Medicinal Products and Other Forms of Interaction).

The risk for developing hyponatremic encephalopathy is increased, for example, in pediatric patients, in women (in particular, premenopausal women), in patients with hypoxemia, and in patients with underlying central nervous system disease.

**Use in patients at risk for sodium retention, fluid overload and edema - Potassium Chloride (10mmol/L-40mmol/L) in 2.5-5% Dextrose and 0.18-0.45% Sodium Chloride Injection, USP**

- Potassium Chloride in Dextrose and Sodium Chloride Injection, USP should be used with particular caution, in patients with or at risk for:
  - hypervolemia
  - conditions that may cause sodium retention, fluid overload and edema (central and peripheral)
    - Primary hyperaldosteronism,
    - Secondary hyperaldosteronism associated with, for example,
      - Hypertension,
      - congestive heart failure,
      - liver disease (including cirrhosis),
      - renal disease (including renal artery stenosis, nephrosclerosis)
    - Pre-eclampsia
- Medications that may increase the risk of sodium and fluid retention, such as corticosteroids

**Use in patients at risk for sodium retention, fluid overload and edema- Potassium Chloride (20 mmol/L- 40mmol/L) in 5% Dextrose and 0.9% Sodium Chloride Injection, USP)**

- Potassium Chloride in Dextrose and Sodium Chloride Injection, USP should be used with particular caution, in patients with or at risk for:
  - hypervolemia
  - conditions that may cause sodium retention, fluid overload and edema (central and peripheral)
    - Primary hyperaldosteronism,
    - Secondary hyperaldosteronism associated with, for example,
      - Hypertension,
      - congestive heart failure,
      - liver disease (including cirrhosis),
      - renal disease (including renal artery stenosis, nephrosclerosis)
    - Pre-eclampsia
  - Hyponatremia
  - Hyperchloremia

➤ Metabolic acidosis

- Medications that may increase the risk of sodium and fluid retention, such as corticosteroids

**Risk of Hypo and Hyperosmolality, serum electrolytes and water imbalance – All Potassium Chloride in Dextrose and Sodium Chloride Injection, USP, Products**

Depending on the volume and rate of infusion and depending on a patient's underlying clinical condition and capability to metabolize dextrose, intravenous administration of Potassium Chloride in Dextrose and Sodium Chloride Injection, USP can cause:

- Hyperosmolality, osmotic diuresis and dehydration
- Electrolyte disturbances such as
  - Hyponatremia
  - Hypophosphatemia,
  - Hypomagnesemia,
- Overhydration/Hypervolemia and, for example, congested states, including central and peripheral edema.

**Risk of Hypo and Hyperosmolality, serum electrolytes and water imbalance – Potassium Chloride (10mmol/L-40mmol/L) in 2.5-5% Dextrose and 0.18-0.45% Sodium Chloride Injection, USP**

Depending on the volume and rate of infusion and depending on a patient's underlying clinical condition and capability to metabolize dextrose, intravenous administration of Potassium Chloride (10mmol/L-40mmol/L) in 2.5-5% Dextrose and 0.18-0.45% Sodium Chloride Injection, USP can cause:

- Hypoosmolality
- 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 or the rate of administration warrants such evaluation.

**Risk of Hypo and Hyperosmolality, serum electrolytes and water imbalance – Potassium Chloride (20mmol/L-40mmol/L) in 5% Dextrose and 0.9% Sodium Chloride Injection, USP**

Depending on the volume and rate of infusion and depending on a patient's underlying clinical condition and capability to metabolize dextrose, intravenous administration of Potassium Chloride (20mmol/L-40mmol/L) in 5% Dextrose and 0.9% Sodium Chloride Injection, USP can cause:

- Acid-base imbalance
- An increase in serum glucose concentration is associated with an increase in serum osmolality. Osmotic diuresis associated with hyperglycemia can result in or contribute to the development of dehydration and electrolyte losses.

### **Use in patients at risk for sodium imbalance**

Potassium Chloride (20mmol/L-40mmol/L) in 5% Dextrose and 0.9% Sodium Chloride Injection, USP is a hypertonic solution. See Table 1 for information on the products' osmolality. In the body, however, glucose containing fluids can become extremely physiologically hypotonic due to rapid glucose metabolism. Monitoring of serum sodium is particularly important for hypotonic fluids.

Depending on the tonicity of the solution, the volume and rate of infusion, and depending on a patient's underlying clinical condition and capability to metabolize glucose, intravenous administration of glucose can cause electrolyte disturbances, most importantly hypo- and hyperosmotic hyponatremia.

High volume infusion must be used under specific monitoring in patients with cardiac or pulmonary failure, and in patients with non-osmotic vasopressin release (including SIADH), due to the risk of hospital-acquired hyponatremia.

Potassium Chloride (20mmol/L-40mmol/L) in 5% Dextrose and 0.9% Sodium Chloride Injection, USP should be used with particular caution, in patients with or at risk for hyponatremia, for example, in children, in elderly patients, in women, postoperatively, in persons with psychogenic polydipsia, and in patients treated with medications that increase the risk of hyponatremia (See Interactions with Other Medicinal Products and Other Forms of Interaction).

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

### **Hyperglycemia**

Rapid administration of dextrose solutions may produce substantial hyperglycemia which may result in or contribute to electrolyte losses, dehydration and hypovolemia due to osmotic diuresis and hyperosmolar syndrome. Hyperglycemia may increase the risk of cardiac complications, infection, systemic sepsis, acute renal failure and even death in certain clinical conditions, especially in acute stress conditions. In order to avoid

hyperglycemia the infusion rate should not exceed the patient's ability to utilize glucose. To reduce the risk of hyperglycemia-associated complications, the infusion rate must be adjusted and/or insulin administered if blood glucose levels exceed levels considered acceptable for the individual patient.

Intravenous dextrose should be administered 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),
- severe malnutrition (risk of precipitating a refeeding syndrome),
- thiamine deficiency, (risk of severe lactic acidosis due to 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 Dextrose and Sodium Chloride 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.
- Newborns (See Pediatric glycemia-related issues).

Prolonged intravenous administration of dextrose and associated hyperglycemia may result in decreased rates of glucose-stimulated insulin secretion.

### **Hyperkalemia**

Potassium Chloride in Dextrose and Sodium Chloride Injection, USP should be administered with caution, to 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 AV block (especially if they receive digitalis),
- potassium-aggravated skeletal muscle channelopathies (e.g., hyperkalemic periodic paralysis, paramyotonia congenita, and potassium-aggravated myotonia/paramyotonia).



Potassium Chloride in Dextrose and Sodium Chloride Injection, USP should be administered 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.

Other groups of patients in whom Potassium Chloride in Dextrose and Sodium Chloride Injection, USP should be used with caution include 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.

### **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.

### **Use in Patients with or at risk of Severe Renal Impairment**

Potassium Chloride in Dextrose and Sodium Chloride Injection, USP should be administered with particular caution, to patients with or, at risk of severe renal impairment. In such patients, administration of Potassium Chloride in Dextrose and Sodium Chloride Injection, USP may result in sodium retention, fluid overload, and/or may predispose to hyperkalemia.

### **Pediatric Use**

The infusion rate and volume depends on the age, weight, clinical and metabolic conditions of the patient, concomitant therapy, and should be determined by a consulting physician experienced in pediatric intravenous fluid therapy.

### **Pediatric glycemia-related issues**

Newborns, 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 dextrose solutions 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, increased oxygen requirements, bronchopulmonary dysplasia, prolonged length of hospital stay, and death.

### **Pediatric Hyponatremia-related issues**

Children (including neonates and older children) are at increased risk of developing hyponatremia as well as for developing hyponatremic encephalopathy.

Plasma electrolyte concentrations should be closely monitored in the pediatric population as this population may have impaired ability to regulate fluids and electrolytes. 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.

The infusion of hypotonic fluids together with the non-osmotic secretion of ADH may result in hyponatremia (specific to Potassium Chloride (10mmol/L-40mmol/L) in 2.5-5% Dextrose and 0.18-0.45% Sodium Chloride Injection, USP).

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

### **Fructose**

This product may contain fructose as an impurity in the dextrose material. Exercise caution when this product is used in patients with hereditary fructose intolerance. In these patients, fructose may result in hypoglycemia, metabolic acidosis, liver toxicity which manifests as vomiting, nausea, sweating, jaundice, hemorrhage, seizures or coma or even death. The severity of the reactions is dependent on the amount and duration of fructose intake.

## **Precautions**

### **Blood**

#### **Potassium Chloride (10mmol/L-40mmol/L) in 5% Dextrose and Sodium Chloride Injection, USP):**

Potassium Chloride in Dextrose and Sodium Chloride Injection, USP should not be administered simultaneously with blood through the same administration set because of the

possibility of pseudoagglutination or hemolysis.

**Potassium Chloride (10mmol/L-40mmol/L) in 3.3% Dextrose and Sodium Chloride Injection, USP):**

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

**Risk of Air Embolism**

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.

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.

**Geriatric Use**

When selecting the type of infusion solution and the volume/rate of infusion for a geriatric patient, consider that geriatric patients are generally more likely to have cardiac, renal, hepatic, and other diseases or concomitant drug therapy.

**Other**

Caution must be exercised in the administration of Potassium Chloride in Dextrose and Sodium Chloride Injection, USP to patients receiving corticosteroids or corticotropin.

Potassium Chloride in Dextrose and Sodium Chloride Injection, USP should be used with caution in patients with overt or subclinical diabetes mellitus.

**Interactions with Other Medicinal Products and Other Forms of Interaction**

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

Caution is advised in patients treated with lithium. Renal sodium and lithium clearance may be increased during administration of Potassium Chloride in Dextrose and Sodium Chloride Injection, USP and can result in decreased lithium levels.

Potassium Chloride in Dextrose and Sodium Chloride 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.

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.

Caution is advised when administering Potassium Chloride in Dextrose and Sodium Chloride Injection, USP to patients treated with drugs leading to an increased vasopressin effect. The below listed drugs increase the vasopressin effect, leading to reduced renal electrolyte free water excretion and may increase the risk of hyponatremia following treatment with i.v. fluids. (See Special Warnings and Precautions for Use and Adverse Reactions)

Drugs stimulating vasopressin release such as chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors (SSRIs), 3,4-methylenedioxy-N-methamphetamine, ifosfamide, antipsychotics, opioids.

Drugs potentiating vasopressin action such as chlorpropamide, non-steroidal anti-inflammatories (NSAIDs), cyclophosphamide.

Vasopressin analogues such as desmopressin, oxytocin, vasopressin, terlipressin.

Caution is advised when administering Potassium Chloride in Dextrose and Sodium Chloride Injection, USP to patients treated with drugs that may increase the risk of hyponatremia, such as diuretics and antiepileptics (e.g. oxcarbazepine).

Regarding medications that increase the risk of sodium and fluid retention, see Special Warnings and Precautions for Use.

### **Pregnancy: Teratogenic Effects**

Pregnancy Category C. Animal reproduction studies have not been conducted with Potassium Chloride in Dextrose and Sodium Chloride Injection, USP. It is also not known

whether Potassium Chloride in Dextrose and Sodium Chloride Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Potassium Chloride in Dextrose and Sodium Chloride Injection, USP should be given to a pregnant woman only if clearly needed.

### **Intrapartum**

Intrapartum maternal intravenous dextrose infusion may result in fetal hyperglycemia and metabolic acidosis as well as rebound neonatal hypoglycemia due to fetal insulin production. The physician should carefully consider the potential risks and benefits for each specific patient before administering Potassium Chloride in Dextrose and Sodium Chloride Injection, USP.

### **Adverse Reactions**

#### **Post-marketing Adverse Reactions**

The following adverse reactions have been reported in the post-marketing experience:

IMMUNE SYSTEM DISORDERS: Anaphylactic reaction, Hypersensitivity

METABOLISM AND NUTRITION DISORDERS:

- Hyperglycemia

Potassium Chloride (10 mmol/L-40mmol/L) in 2.5-5% Dextrose and 0.18-0.45% Sodium Chloride Injection, USP):

- Hyponatremia

Potassium Chloride (20 mmol/L-40mmol/L) in 5% Dextrose and 0.9% Sodium Chloride Injection, USP)

- Hypernatremia

VASCULAR DISORDERS: Phlebitis

SKIN AND SUBCUTANEOUS TISSUE DISORDERS: Rash, Pruritus

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS:

Injection site reactions including, Infusion site pain, Injection site vesicles, Chills, Pyrexia

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 Reactions (Class Reactions)**

- Hyperkalemia
- Cardiac arrest as a manifestation of rapid intravenous administration and/or of hyperkalemia
- Hyponatremic encephalopathy

#### **Potassium Chloride (20mmol/L-40mmol/L) in 5% Dextrose and 0.9% Sodium Chloride Injection, USP):**

- Hyponatremia, which may be symptomatic (see under the subheading “Hyponatremia” in WARNINGS AND PRECAUTIONS).
- Hyperchloremic Acidosis

### **Overdose**

Excess administration of Potassium Chloride in Dextrose and Sodium Chloride Injection, USP can cause:

- Hyperglycemia, adverse effects on water and electrolyte balance, and corresponding complications. For example, severe hyperglycemia and severe dilutional hyponatremia and their complications, can be fatal.
- Hyponatremia (which can lead to CNS manifestations including seizures, coma, cerebral edema and death).
- Hyponatremia, especially in patients with severe renal impairment (**specific to Potassium Chloride (20 mmol/L-40mmol/L) in 5% Dextrose and 0.9% Sodium Chloride Injection, USP**).
- Fluid overload (which can lead to central and/or peripheral edema).
- Hyperkalemia, 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
  - hypotension
  - muscle weakness up to and including muscular and respiratory paralysis, paresthesia of extremities
  - gastrointestinal symptoms (ileus, nausea, vomiting, abdominal pain)
- Arrhythmias and conduction disorders, in addition to arrhythmias and conduction disorders, the ECG shows progressive changes that occur with increasing potassium levels. Possible changes include:
    - 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. The presence of any ECG findings that are suspected to be caused by hyperkalemia should be considered a medical emergency.
  - See also section Special Warnings and Precautions for Use and Adverse Reactions
  - When assessing an overdose, any additives in the solution must also be considered.
  - Clinically significant overdose of Potassium Chloride in Dextrose and Sodium Chloride Injection, USP may, therefore, constitute a medical emergency.
  - Interventions include discontinuation of Potassium Chloride in Dextrose and Sodium Chloride Injection, USP administration, dose reduction, administration of insulin and other measures as indicated for the specific clinical constellation.

## **Dosage and Administration**

As directed by a physician. Potassium Chloride in Dextrose and Sodium Chloride Injection, USP is for intravenous infusion.

Osmolarity information for Potassium Chloride in Dextrose and Sodium Chloride

Injection, USP, refer to Table 1. Hyperosmolar solutions may cause venous irritation and phlebitis. Thus, any hyperosmolar solutions are recommended to be administered through a large central vein, for rapid dilution of the hyperosmolar solution.

The choice of the specific potassium chloride, sodium chloride, and dextrose concentration, dosage, the infusion rate and duration, and volume depend on the age, weight, clinical and metabolic conditions of the patient, concomitant therapy and should be determined by the consulting physician. For patients with electrolyte and glucose abnormalities and for pediatric patients, a physician experienced in intravenous fluid therapy should be consulted.

Rapid correction of hyponatremia and hypernatremia is potentially dangerous (risk of serious neurologic complications).

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. Do not administer unless the solution is clear and the seal is intact. Use of an in-filter is recommended during administration of all parenteral solutions, where possible.

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

### **Instructions for Use and Handling, and Disposal**

Additives may be incompatible. Complete information is not available. Before adding a substance or medication, verify that it is soluble and/or stable in Potassium Chloride in Dextrose and Sodium Chloride Injection, USP and that the pH range of Potassium Chloride in Dextrose and Sodium Chloride Injection, USP is appropriate. When introducing additives to Potassium Chloride in Dextrose and Sodium Chloride Injection, USP, the instructions for use of the medication to be added and other relevant literature must be consulted. Those additives known or determined 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. After addition, if there is a colour change 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. For single use only. Discard any unused portion.

### **How Supplied**

Potassium Chloride in Dextrose and Sodium Chloride Injection, USP in VIAFLEX plastic container is available as shown in **Table 1**.

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. Store at 15°C to 25°C.

### **Directions for Use of VIAFLEX 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**

**Warning:** Additives may be incompatible.

### **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**

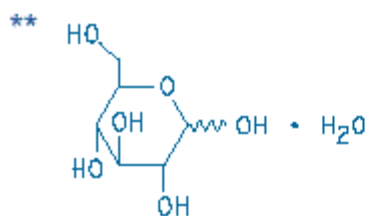
1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by squeezing them while container is in the upright position.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

**Table 1.**

|  | Size | Composition (g/L)      |                      |                               |                         |     | pH  | Ionic Concentration (mmol/L) |           |          | Caloric Conct. (kcal/L) |  |
|--|------|------------------------|----------------------|-------------------------------|-------------------------|-----|-----|------------------------------|-----------|----------|-------------------------|--|
|  |      | Dextrose Hydrrous, USP | Sodium Chloride, USP | Potassium Chloride, USP (KCl) | **Osmolarity (mOsmol/L) |     |     | Sodium                       | Potassium | Chloride |                         |  |
| Potassium Chloride in 5% Dextrose and 0.2% Sodium Chloride Injection, USP    | mL   |                        |                      |                               |                         |     |     |                              |           |          |                         |  |
| *** 20 mmol/L  | 1000 | 50                     | 2.0                  | 1.5                           | 361                     | 4.0 | 34  | 20                           | 54        | 170      |                         |  |
| Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection, USP   |      |                        |                      |                               |                         |     |     |                              |           |          |                         |  |
| 20mmol/L   | 1000 | 50                     | 4.5                  | 1.5                           | 447                     | 4.0 | 77  | 20                           | 97        | 170      |                         |  |
| 40mmol/L   | 1000 | 50                     | 4.5                  | 3                             | 487                     | 4.0 | 77  | 40                           | 117       | 170      |                         |  |
| Potassium Chloride in 5% Dextrose and 0.9% Sodium Chloride Injection, USP    |      |                        |                      |                               |                         |     |     |                              |           |          |                         |  |
| 20mmolL  | 1000 | 50                     | 9.0                  | 1.5                           | 601                     | 4.5 | 154 | 20                           | 174.1     | 170      |                         |  |
| 40mmolL  | 1000 | 50                     | 9.0                  | 1.5                           | 641                     | 4.5 | 154 | 40                           | 194.1     | 170      |                         |  |
| Potassium Chloride in 3.3% Dextrose and 0.33% Sodium Chloride Injection, USP |      |                        |                      |                               |                         |     |     |                              |           |          |                         |  |
| 20mmol/L   | 1000 | 33                     | 3                    | 1.5                           | 309                     | 4.0 | 51  | 20                           | 71        | 112      |                         |  |
| 40mmol/L   | 1000 | 33                     | 3                    | 3                             | 349                     | 4.0 | 51  | 40                           | 91        | 112      |                         |  |

\*\*Normal physiologic osmolarity range is approximately 280 to 310 mOsmol/L. Administration of substantially hypertonic solutions (> 600 mOsmol/L) may cause vein damage.

\*\*\* DO not administer these injections simultaneously with blood.



D-Glucose monohydrate

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