

## 0.15% Potassium Chloride in 0.9% Sodium Chloride Injection

### DESCRIPTION

**Rx only**

Each 100 mL of **0.15% Potassium Chloride in 0.9% Sodium Chloride Injection (20 mEq K<sup>+</sup>/liter)**

contains: Sodium Chloride USP 0.9 g

Potassium Chloride USP 0.15 g; Water for Injection USP qs

pH may be adjusted with Hydrochloric Acid NF

pH: 5.6 (3.5-6.5)

Calculated Osmolarity: 350 mOsmol/liter

Concentration of Electrolytes (mEq/liter):

Sodium 154                  Potassium 20                  Chloride 174

0.15% Potassium Chloride in 0.9% Sodium Chloride Injection is sterile, nonpyrogenic, hypertonic and contains no bacteriostatic or antimicrobial agents. This product is intended for intravenous administration.

The formulas of the active ingredients are:

| <b>Ingredients</b>     | <b>Molecular Formula</b> | <b>Molecular Weight</b> |
|------------------------|--------------------------|-------------------------|
| Sodium Chloride USP    | NaCl                     | 58.44                   |
| Potassium Chloride USP | KCl                      | 74.55                   |

The EXCEL Container is Latex-free, PVC-free, and DEHP-free.

The plastic container is made from a multilayered film specifically developed for parenteral drugs. It contains no plasticizers and exhibits virtually no leachables. The solution contact layer is a rubberized copolymer of ethylene and propylene. The container is nontoxic and biologically inert. The container-solution unit is a closed system and is not dependent upon entry of external air during administration. The container is overwrapped to provide protection from the physical environment and to provide an additional moisture barrier when necessary.

Addition of medication should be accomplished using complete aseptic technique.

The closure system has two ports; the one for the administration set has a tamper evident plastic protector and the other is a medication addition site. Refer to the Directions for Use of the container.

### CLINICAL PHARMACOLOGY

0.15% Potassium Chloride in 0.9% Sodium Chloride Injection provides electrolytes and is a source of water for hydration. It is capable of inducing diuresis depending on the clinical condition of the patient.

Sodium, the major cation of the extracellular fluid, functions primarily in the control of water distribution, fluid balance, and osmotic pressure of body fluids. Sodium is also associated with chloride and bicarbonate in the regulation of acid-base equilibrium of body fluid.

Potassium, the principal cation of intracellular fluid, participates in carbohydrate utilization and protein synthesis, and is critical in the regulation of nerve conduction and muscle contraction, particularly in the heart.

Chloride, the major extracellular anion, closely follows the metabolism of sodium, and changes in the acid-base balance of the body are reflected by changes in the chloride concentration.

## **INDICATIONS AND USAGE**

0.15% Potassium Chloride in 0.9% Sodium Chloride Injection is indicated for use in adults and pediatric patients as a source of electrolytes and water for hydration.

## **CONTRAINDICATIONS**

0.15% Potassium Chloride in 0.9% Sodium Chloride Injection is contraindicated in clinical conditions where additives of sodium, potassium or chloride could be clinically detrimental.

## **WARNINGS**

The administration of intravenous solutions can cause fluid and/or solute overload 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. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentration.

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 is sodium retention with edema.

Infusion of isotonic (0.9%) sodium chloride during or immediately after surgery may result in excessive sodium retention. Use the patient's circulatory system status as a guide.

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

Solutions containing 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.

## **PRECAUTIONS**

### **General**

This solution should be used with care in patients with hypervolemia, renal insufficiency, urinary tract obstruction, or impending or frank cardiac decompensation.

Extraordinary electrolyte losses such as may occur during protracted nasogastric suction, vomiting, diarrhea or gastrointestinal fistula drainage may necessitate additional electrolyte supplementation.

Additional essential electrolytes, minerals, and vitamins should be supplied as needed.

Sodium-containing solutions should be administered with caution to patients receiving corticosteroids or corticotropin, or to other salt-retaining patients.

Infusion of more than one liter of isotonic (0.9%) sodium chloride may supply more sodium and chloride than normally found in serum, and can exceed normal tolerance, resulting in hypernatremia; this may also cause a loss of bicarbonate ions, resulting in an acidifying effect.

**Potassium therapy should be guided primarily by serial electrocardiograms, especially in patients receiving digitalis. Serum potassium levels are not necessarily indicative of tissue potassium levels.**

Solutions containing potassium should be used with caution in the presence of cardiac disease, particularly when accompanied by renal disease.

Care should be exercised in administering solutions containing sodium or potassium to patients with renal or cardiovascular insufficiency, with or without congestive heart failure, particularly if they are postoperative or elderly.

To minimize the risk of possible incompatibilities arising from mixing this solution with other additives that may be prescribed, the final infusate should be inspected for cloudiness or precipitation immediately after mixing, prior to administration, and periodically during administration.

Do not use plastic container in series connection.

If administration is controlled by a pumping device, care must be taken to discontinue pumping action before the container runs dry or air embolism may result.

This solution is intended for intravenous administration using sterile equipment. It is recommended that intravenous administration apparatus be replaced at least once every 24 hours.

Use only if solution is clear and container and seals are intact.

### **Laboratory Tests**

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. Significant deviations from normal concentrations may require tailoring of the electrolyte pattern, in this or alternative solutions.

### **Carcinogenesis, Mutagenesis, Impairment of Fertility**

Studies with 0.15% Potassium Chloride in 0.9% Sodium Chloride Injection have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

### **Pregnancy: Teratogenic Effects**

Pregnancy Category C. Animal reproduction studies have not been conducted with 0.15% Potassium Chloride in 0.9% Sodium Chloride Injection. It is also not known whether 0.15% Potassium Chloride in 0.9% Sodium Chloride Injection can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. 0.15% Potassium Chloride in 0.9% Sodium Chloride Injection should be given to a pregnant woman only if clearly needed.

### **Labor and Delivery**

The effects of Potassium Chloride in Sodium Chloride Injections USP on the duration of labor or delivery, on the possibility that forceps delivery or other intervention or resuscitation of the newborn will be necessary, and on the later growth, development, and functional maturation of the child are unknown.”

As reported in the literature, potassium containing solutions have been administered during labor and delivery. Caution should be exercised, and the fluid balance, glucose and electrolyte concentrations, and acid-base balance, of both mother and fetus should be evaluated periodically or whenever warranted by the condition of the patient or fetus.

### **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 0.15% Potassium Chloride in 0.9% Sodium Chloride Injection is administered to a nursing woman.

### **Pediatric Use**

Safety and effectiveness of Potassium Chloride in Sodium Chloride 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.

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

In neonates or in very small infants even small volumes of fluid may affect fluid and electrolyte balance. Care must be exercised in treatment of neonates, especially pre-term neonates, whose renal function may be immature and whose ability to excrete fluid and solute loads may be limited. Fluid intake, urine output, and serum electrolytes should be monitored closely.

See **WARNINGS** and **DOSAGE AND ADMINISTRATION**.

### **Geriatric Use**

Clinical studies of Potassium Chloride in Sodium Chloride 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 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.

See **WARNINGS**.

### **ADVERSE REACTIONS**

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.

Too rapid infusion of hypertonic solutions may cause local pain and venous irritation. Rate of administration should be adjusted according to tolerance. Use of the largest peripheral vein and a small bore needle is recommended. (See **DOSAGE AND ADMINISTRATION**.)

Symptoms may result from an excess or deficit of one or more of the ions present in the solution; therefore, frequent monitoring of electrolyte levels is essential.

Hypernatremia may be associated with edema and exacerbation of congestive heart failure due to the retention of water, resulting in an expanded extracellular fluid volume.

Reactions reported with the use of potassium-containing solutions include nausea, vomiting, abdominal pain and diarrhea. The signs and symptoms of potassium intoxication include paresthesias of the extremities, areflexia, muscular or respiratory paralysis, mental confusion, weakness, hypotension, cardiac arrhythmias, heart block, electrocardiographic abnormalities and cardiac arrest. Potassium deficits result in disruption of neuromuscular function, and intestinal ileus and dilatation.

If infused in large amounts, chloride ions may cause a loss of bicarbonate ions, resulting in an acidifying effect.

The physician should also be alert to the possibility of adverse reactions to drug additives. Prescribing information for drug additives to be administered in this manner should be consulted.

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.

### **OVERDOSAGE**

In the event of a fluid or solute overload during parenteral therapy, reevaluate the patient's condition and institute appropriate corrective treatment.

In the event of overdosage with potassium-containing solutions, discontinue the infusion immediately and institute corrective therapy to reduce serum potassium levels.

Treatment of hyperkalemia includes the following:

1. Dextrose Injection USP, 10% or 25% containing 10 units of crystalline insulin per 20 grams of dextrose administered intravenously, 300 to 500 mL per hour.
2. Absorption and exchange of potassium using sodium or ammonium cycle cation exchange resin, orally and as retention enema.
3. Hemodialysis and peritoneal dialysis. The use of potassium-containing foods or medications must be eliminated. However, in cases of digitalization, too rapid a lowering of plasma potassium concentration can cause digitalis toxicity.

### **DOSAGE AND ADMINISTRATION**

This solution is for intravenous use only.

Dosage is to be directed by a physician and is dependent upon age, weight, clinical condition of the patient and laboratory determinations. Frequent laboratory determinations and clinical evaluation are essential to monitor changes in blood glucose and electrolyte concentrations, and fluid and electrolyte balance during prolonged parenteral therapy.

When a hypertonic solution is to be administered peripherally, it should be slowly infused through a small bore needle, placed well within the lumen of a large vein to minimize venous irritation. Carefully avoid infiltration.

In the average adult, daily requirements of sodium and chloride are met by the infusion of one liter of 0.9% sodium chloride (154 mEq each of sodium and chloride).

Usually up to 40 mEq of potassium per liter daily is sufficient to replace normal loss in adults. Infusion rates should not exceed 10 mEq per hour or 120 mEq per day. A liter of fluid containing 40 mEq of potassium should be administered over an 8-hour period.

Fluid administration should be based on calculated maintenance or replacement fluid requirements for each patient.

**Pediatric Dosage and Administration .** There is no specific pediatric dose. The dose is dependent on weight, clinical condition and laboratory results. See **WARNINGS** and **PRECAUTIONS**.

Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

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

### **HOW SUPPLIED**

0.15% Potassium Chloride in 0.9% Sodium Chloride Injection is supplied sterile and nonpyrogenic in EXCEL® Containers packaged 12 per case.

**NDC**

**Cat. No.**

**Size**

NDA 19-708/S-013

Page 8

0.15% Potassium Chloride in 0.9% Sodium Chloride Injection  
(20 mEq K<sup>+</sup>/liter)

0264-7865-00

L8650

1000 mL

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

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U.S. Patent No. 4,803,102

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### **Directions for Use of EXCEL® Container**

**Caution :** Do not use plastic container in series connection.

#### **To Open**

Tear overwrap down at notch and remove solution container. Check for minute leaks by squeezing solution container firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below before preparing for administration.

**NOTE:** Before use, perform the following checks:

Inspect each container. Read the label. Ensure solution is the one ordered and is within the expiration date.

**INVERT CONTAINER AND CAREFULLY INSPECT THE SOLUTION IN GOOD LIGHT FOR CLOUDINESS, HAZE, OR PARTICULATE MATTER. ANY CONTAINER WHICH IS SUSPECT SHOULD NOT BE USED.**

Use only if solution is clear and container and seals are intact.

#### **Preparation for Administration**

1. Remove plastic protector from sterile set port at bottom of container.
2. Attach administration set. Refer to complete directions accompanying set.

#### **To Add Medication**

**Warning:** Some additives may be incompatible.

#### **To Add Medication Before Solution Administration**

1. Prepare medication site.
2. Using syringe with 18-22 gauge needle, puncture medication port and inner diaphragm and inject.
3. Squeeze and tap ports while ports are upright and mix solution and medication thoroughly.

#### **To Add Medication During Solution Administration**

1. Close clamp on the set.
2. Prepare medication site.
3. Using syringe with 18-22 gauge needle of appropriate length (at least 5/8 inch), puncture resealable medication port and inner diaphragm and inject.
4. Remove container from IV pole and/or turn to an upright position.
5. Evacuate both ports by tapping and 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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