**DESCRIPTION**

Kionex®, brand of sodium polystyrene sulfonate is a benzene, diethyl-polymer, with ethyl-
benzene, sulfonated, sodium salt, a following structural formula:

\[
\text{SO}_3^-\text{Na}^+ + \text{CH}_2-\text{CH}_2\ 
\]

The drug is a cream to light brown finely ground, powdered form of sodium polystyrene sulfonate, a cation exchange resin used in the sodium phase with an in vitro exchange capacity of approximately 3.1 mEq (in vivo approximately 1 mEq) of potassium per gram. The sodium content is approximately 100 mEq (in vitro) per gram of the drug. It can be administered orally or in an enema.

**CLINICAL PHARMACOLOGY**

As the resin passes along the intestine or is retained in the colon after administration by enema, the potassium ions are replaced by sodium ions. For the most part, this action occurs in the large intestine, which excretes potassium ions to a greater degree than does the small intestine. The efficiency of this process is limited and unpredictable variable. It commonly approximates the order of 50% but the range is so large that definite indices of electrolyte balance must be clearly monitored.

**INDICATIONS AND USAGE**

Kionex® is indicated for the treatment of hyperkalemia.

**CONTRAINDICATIONS**

Kionex® is contraindicated in the following conditions: patients with hypokalemia, patients with a history of hypersensitivity to polystyrene sulfonate resins, obstructive bowel disease, neonates with reduced gut motility (postoperatively or drug induced) and oral administration in neonates (see PRECAUTIONS).

**WARNINGS**

**Intestinal Necrosis:** Cases of intestinal necrosis, which may be fatal, and other serious gastrointestinal adverse events (bleeding, ischemic colitis, perforation) have been reported in association with sodium polystyrene sulfonate use. The majority of these cases reported the concomitant use of sorbitol. Risk factors for gastrointestinal adverse events were present in many of the cases including prolonged history of intestinal disease or surgery, hypokalemia, and renal insufficiency and failure. Concomitant administration of sorbitol is not recommended (see PRECAUTIONS, Drug Interactions).

• Use only in patients who have normal bowel function. Avoid use in patients who have not had a bowel movement post-surgery.

• Avoid use in patients who are at risk for developing constipation or impaction (including those with history of hypokalemia, chronic constipation, inflammatory bowel disease, ischemic colitis, vascular intussusception, previous bowel resection, or bowel obstruction).

• Discontinue use in patients who develop constipation.

**Alternative Treatment for Severe Hyperkalemia:** Since effective lowering of serum potassium within 24 hours may take hours to days, treatment with this drug alone may be insufficient to rapidly correct severe hyperkalemia associated with states of rapid tissue breakdown (e.g., burns and rnal failure). Potassium supplements in hypertensive patients should be closely monitored and adjusted in these patients. Electrocardiographic changes may be consistent with hypokalemia or hypocalcemia; cardiac arrhythmias may occur. Measures should be taken to correct electrocardiographic changes when they occur. The intensity and duration of therapy depend upon the severity and resistance of hyperkalemia. Measures, including dialysis, should always be considered and may be imperative.

**Hypokalemia:** Serious potassium deficiency can occur from therapy with Kionex®. The effect must be carefully controlled by frequent serum potassium determinations within each 24 hour period. Since intracellular potassium deficiency is not always reflected by serum potassium levels, the level at which treatment with Kionex® should be discontinued must be determined individually for each patient. Important aids in making this determination are the patient’s clinical condition and electrocardiogram. Early clinical signs of severe hypokalemia include a pattern of irritable confusion and delayed thought processes.

**Electrolyte Disturbances:** Like all cation-exchange resins, Kionex® Sodium Polystyrene Sulfonate is not totally selective (for potassium) in its actions, and small amounts of other cations such as magnesium and calcium can also be lost during treatment. Accordingly, patients receiving Kionex® should be monitored for all applicable electrolyte disturbances. Studies have not been performed. As the resin passes along the intestine or is retained in the colon after administration by enema, the potassium ions are replaced by sodium ions. For the most part, this action occurs in the large intestine, which excretes potassium ions to a greater degree than does the small intestine. The efficiency of this process is limited and unpredictable variable. It commonly approximates the order of 50% but the range is so large that definite indices of electrolyte balance must be clearly monitored.

**Metabolic Data are Unavailable.**

**Drug Interactions**

Non-absorbable cation-donating antacids and laxatives:

• Sorbitol: Concomitant use of sorbitol with sodium polystyrene sulfonate has been implicated in cases of intestinal necrosis which may be fatal. Therefore, concomitant administration is not recommended (see WARNINGS).

**Lithium:** Kionex® may decrease absorption of lithium.

**Thyroxine:** Kionex® may decrease absorption of thyroxine.

**Carcinogenesis, Mutagenesis, Impairment of Fertility:**

Studies have not been performed.

**Pregnancy Category C**

Animal reproduction studies have not been conducted with Kionex® Sodium Polystyrene Sulfonate, USP. It is not known whether Kionex® can cause fetal harm when administered to pregnant women or can affect reproduction capacity. Kionex® should be given to a pregnant woman only if clearly needed.

**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 Kionex® is administered to a nursing woman.

**Pediatric Use**

The effectiveness of Kionex® in pediatric patients has not been established. In neonates, Kionex® should not be given by the oral route. In both children and neonates, particular care should be observed with oral administration, as excessive dosage or inadequate dilution could result in impactation of the resin.

**ADVERSE REACTIONS**

Kionex® Sodium Polystyrene Sulfonate may cause some degree of gastric irritation. Anorexia, nausea, vomiting, and constipation may occur especially if high doses are given. Also, hypokalemia, hypocalcemia, hypomagnesemia and significant sodium retention, and their related clinical manifestations, may occur (see WARNINGS). Occasionally diarrhea develops. Large doses in elderly individuals may cause fecal impaction (see PRECAUTIONS). Rare instances of intestinal necrosis have been reported. Intestinal obstruction due to concretions of aluminum hydroxide, when used in combination with sodium polystyrene sulfonate, has been reported.

The following events have been reported from worldwide post marketing experience:

• Fecal impaction following rectal administration, particularly in children;

• Gastrointestinal constrictions (bezoars) following oral administration;

• Ischemic colitis, gastrointestinal tract ulceration or necrosis which could lead to intestinal perforation; and,

• Rare cases of acute bronchitis and/or broncho-pneumonia associated with inhalation of particles of polystyrene sulfonate.

**OVERDOSE**

Overdose may result in electrolyte disturbances including hypocalkemia, hypocalcemia, and hypomagnesemia. Biochemical disturbances resulting from overdose may give rise to clinical signs and symptoms of hypokalemia, including: irritability, confusion, delayed thought processes, muscle weakness, hyporeflexia, which may progress to frank paralysis and/or apnea. Tinitus may occur. Electrocardiographic changes may be consistent with hypocalcemia or hypocalcemia; cardiac arrhythmias may occur. Appropriate measures should be taken to correct serum electrolytes (potassium, calcium, magnesium), and the resin should be removed from the alimentary tract by appropriate use of laxatives or enemas.

**DOSAGE AND ADMINISTRATION**

Suspension of this drug should be freshly prepared and not stored beyond 24 hours.

The average adult dose of the resin is 15 to 60 g. This is best provided by administering 15 g (approximately 4 level teaspoon) of Kionex® one to four times daily. One gram of Kionex® contains 4.1 mEq of sodium; one level teaspoon contains approximately 3.5 g of Kionex® and 15 mEq of sodium (a heaping teaspoon may contain as much as 10 g to 12 g of Kionex®). Since the in vivo efficiency of sodium-polystyrene exchange resins is approximately 33 percent, about one third of the resin’s actual sodium content is being delivered to the body.

In neonates, children under 4 years of age, or elderly patients, the dose should be reduced by using as a guide a rate of 1 mEq of potassium per gram of resin as the basis for calculation.

Each dose should be given as a suspension in a small quantity of water or, for greater palatability, in syrup. The amount of fluid usually ranges from 20 mL to 100 mL, depending on the dose, or may be simply determined by allowing 3 mL to 4 mL per gram of resin. Healthcare professionals should follow full aspiration precautions when administering this product, such as placing and maintaining the patient in an upright position while the resin is being administered.

The resin may be introduced into the stomach through a plastic tube or, if desired, mixed with a diet appropriate for a patient in a recent failure.

The resin may also be given, although with less effective results, in an enema consisting (for adults) of 30 mL to 40 mL every six hours. Each dose is administered as a warm emulsion (at body temperature) in 100 mL of aqueous vehicle. The emulsion should be agitation gently during administration. The emulsion should be retained in the colon as long as possible and followed by a cleansing enema. After an initial cleansing enema, a soft, large (French 28) rubber tube is inserted into the rectum for a distance of about 20 cm, with the tip well into the sigmoid colon, and tamped in place. The resin is then introduced into the appropriate apparatus vehicle at body temperature and introduced by gravity, while the particles are kept in suspension by stirring. The suspension is flushed with 50 mL or 100 mL of fluid, following which the tube is clamped and left in place. If back leakage occurs, the tube should be released or the patient’s knees position is taken temporarily. Asomewhat thicker suspension may be used, but care should be taken that no paste is formed, because the latter has a greatly reduced exchange surface and will be particularly ineffective if deposited in the rectal ampulla. The suspension is kept in the sigmoid colon for several hours, if possible. Then, the colon is irrigated with sodium-containing solution at body temperature in order to remove the resin. Two quarts of flushing solution may be necessary. The returns are drained constantly through a Y tube connection. While the use of sorbitol is not recommended, particular attention should be paid to this cleansing enema if sorbitol has been used.

The intensity and duration of therapy depend upon the severity and resistance of hypokalemia.

Kionex® should not be heated for to do so may alter the exchange properties of the resin.

**HOW SUPPLIED**

Kionex® is available as a cream in light brown, finely ground powder in jars of 1 pound. Store at 20° to 25°C (68° to 77°F) (see USP Controlled Room Temperature). Kionex® (Sodium Polystyrene Sulfonate, USP) is available as a powder in containers of: 245 grams (One Pound) NDC: 0574-2044-16 Rx only

**Packaged By**

Perigo

Minneapolis, MN 55427

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