Sodium Polystyrene Sulfonate for Suspension

Cation-Exchange Resin

DESCRIPTION
Sodium polystyrene sulfonate is a benzene, diethenyl-polymer, with ethenylbenzene, sulfonated, sodium salt and has the following structural formula:

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\begin{align*}
\text{C}_9\text{H}_7\text{SO}_3^- + \text{Na}^+ & \rightarrow \text{C}_9\text{H}_7\text{SO}_3^- + \text{Na}^+ \\
\text{C}_9\text{H}_7\text{Cl}^- & \rightarrow \text{C}_9\text{H}_7\text{Cl}^- \\
\text{C}_9\text{H}_7\text{H}_2^+ & \rightarrow \text{C}_9\text{H}_7\text{H}_2^+ \\
\end{align*}
\]

The drug is a golden brown finely-ground, powdered form of sodium polystyrene sulfonate, a cation-exchange resin prepared in the sodium phase with an in vitro exchange capacity of approximately 3.1 mEq (or approximately 1.5 mEq) of potassium per gram. The sodium content is approximately 100 mg (4.1 mEq) 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 sodium ions are partially released and are replaced by potassium 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. It commonly approximates the order of 33 percent but the range is so large that definitive indices of electrolyte balance must be clearly monitored.

Metabolic data are unavailable.

INDICATIONS AND USAGE
Sodium polystyrene sulfonate for suspension is indicated for the treatment of hyperkalemia.

CONTRAINDICATIONS
Sodium polystyrene sulfonate is contraindicated in the following conditions: patients with hypokalemia, patients with a history of hypersensitivity to polystyrene sulfonate resins, obstructive bowel disease, renal insufficiency and failure. Concomitant cases including prematurity, history of intestinal disease or surgery, hypovolemia, and hypokalemia may take hours to days, treatment with this drug alone may be impractical. Hypokalemia include a pattern of irritative confusion and delayed thought processes.

Electrocardiographically, severe hypokalemia is often associated with a lengthened Q-T interval, widening, flattening, or inversion of the T wave, and prominent U waves. Marked hypokalemia can also be manifested by severe muscle weakness, at times extending into frank paralysis.

Electrolyte Disturbances
Like all cation-exchange resins, sodium polystyrene sulfonate is not totally selective (for potassium) in its actions, and small amounts of other cations such as magnesium and sodium can also be lost during treatment. Accordingly, patients receiving sodium polystyrene sulfonate should be monitored for all applicable electrolyte disturbances.

Systemic Alkalosis
Systemic alkalosis has been reported after cation-exchange resins were administered orally in combination with nonabsorbable cation-donating antacids and laxatives such as magnesium hydroxide and aluminum carbonate. Magnesium hydroxide should not be administered with sodium polystyrene sulfonate. One case of grand mal seizure has been reported in a patient with chronic hypokalemia of renal failure who was given sodium polystyrene sulfonate with magnesium hydroxide as laxative (See PRECAUTIONS, Drug Interactions).

PRECAUTIONS

Drug Interactions

Antacids
The simultaneous administration of sodium polystyrene sulfonate with nonabsorbable cation-donating antacids and laxatives may reduce the resin’s potassium exchange capability.

Non-absorbable cation-donating antacids and laxatives
Systemic alkalosis has been reported after cation-exchange resins were administered orally in combination with nonabsorbable cation-donating antacids and laxatives such as magnesium hydroxide and aluminum carbonate. Magnesium hydroxide should not be administered with sodium polystyrene sulfonate. One case of grand mal seizure has been reported in a patient with chronic hypokalemia of renal failure who was given sodium polystyrene sulfonate with magnesium hydroxide as a laxative.

Intestinal obstruction due to concretions of aluminum hydroxide when used in combination with sodium polystyrene sulfonate has been reported.

Diethylther
The toxic effects of digitalis on the heart, especially various ventricular arrhythmias and AV nodal dissociation, are likely to be exaggerated by hypokalemia, even in the face of serum digoxin concentrations in the “normal range” (See WARNINGS, Intestinal Necrosis).

Sorbitol
Concurrent use of Sorbitol with sodium polystyrene sulfonate has been implicated in cases of intestinal necrosis, which may be fatal. Therefore, concurrent administration is not recommended (See WARNINGS).

Lithium
Sodium polystyrene sulfonate may decrease absorption of lithium.

Thyroxine
Sodium polystyrene sulfonate 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 sodium polystyrene sulfonate. It is also not known whether sodium polystyrene sulfonate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium polystyrene sulfonate 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 sodium polystyrene sulfonate is administered to a nursing woman.

Pediatric Use
The effectiveness of sodium polystyrene sulfonate in pediatric patients has not been established. In neonates, sodium polystyrene sulfonate should be given by the oral route. In both children and neonates, particular care should be observed with rectal administration, as excessive dosage or inadequate dilution could result in impaction of the resin.

Due to the risk of digestive hemorrhage or intestinal necrosis, particular care should be observed in premature infants or low birth weight infants.

ADVERSE REACTIONS
Sodium polystyrene sulfonate may cause some degree of gastric irritation. Anorexia, nausea, vomiting, and crampation may occur especially if high doses are given. Also, hypokalemia, hypocalcemia, hypomagnesemia and significant sodium retention, and their related clinical manifestations, may occur. Occasionally diarrhea develops. Large doses in elderly individuals may cause fecal impaction. Rare instances of intestinal obstruction due to concretions of aluminum hydroxide, when used in combination with sodium polystyrene sulfonate, have been reported.

The following events have been reported from worldwide post-marketing experience:
- Fecal impaction following rectal administration, particularly in children;
- Gastrointestinal concretions (bezoars) following oral administration;
- Cardiac arrhythmias, gastrointestinal tract ulceration or necrosis which could lead to intestinal perforation; and,
- Late cases of acute bronchitis and/or broncho-pneumonia associated with inhalation of particles of polystyrene sulfonate.

OVERDOSAGE
Overdosage may result in electrolyte disturbances including hypokalemia, hypocalcemia, and hypomagnesemia. Biochemical disturbances resulting from overdosage 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 syncope. Tachycardia may occur. Electrocardiographic changes may be consistent with hypokalemia 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 daily adult dose of the resin is 15 g to 60 g. This is best provided by administering 15 g (approximately 4 level teaspoons) of sodium polystyrene sulfonate one to four times daily. One gram of sodium polystyrene sulfonate contains 4.1 mEq of sodium; one level teaspoon contains approximately 3.3 g of sodium polystyrene sulfonate and 15 mEq of sodium. A heaping teaspoon may contain as much as 10 g to 12 g of sodium polystyrene sulfonate. Since the in vitro efficiency of sodium-potassium exchange resin is approximately 53 percent, about one third of the resin’s actual sodium content is being delivered to the body.

In smaller children and infants, lower doses should be employed 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 and, if desired, mixed with a diet appropriate for a patient in renal failure.

The resin may also be given, although with less effective results, in an enema consisting (for adults) of 30 g to 50 g every six hours. Each dose is administered as a warm emulsion (at body temperature) in 100 mL of aqueous vehicle. The emulsion should be equilibrated gently during administration. The enema should be retained as long as possible and followed by a cleansing enema.

After an initial cleansing enema, a soft, large size (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 taped in place. The resin is then suspended in the appropriate amount of aqueous vehicle at body temperature and introduced by gravity, while the particle are kept in suspension by stirring. The suspension is flushed with 20 mL or 100 mL of fluid, following which the tube is clamped and left in place. If back leakage occurs, the lips are elevated on pillows or a knee-chest position is taken temporarily. A somewhat 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 salbutal 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 hyperkalemia.

Sodium polystyrene sulfonate should not be heated for too long or too hot, as this may alter the exchange properties of the resin.

HOW SUPPLIED
Sodium polystyrene sulfonate for suspension is available as a golden brown, finely ground powder in jars of 1 pound (454 g). NDC 11534-166-44 and in bottles of 15 g, NDC 11534-166-15.

Store at 25°C (77°F), excursions permitted to 15°C – 30°C (59°F – 86°F).

[SUSPENSION KD USP Controlled Room Temperature]

Rx Only
Manufactured & Distributed by: Sunrise Pharmaceuticals, Inc. Ramsey, NJ 07446

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