The average daily adult dose of the resin is 15 to 50 g. This is best provided by administering 15 g (approximately 4 level teaspoons) of Sodium Polystyrene Sulfonate USP one to four times daily. One gram of Sodium Polystyrene Sulfonate USP contains 4.1 mEq of sodium; one level teaspoon contains approximately 3.5 g of Sodium Polystyrene Sulfonate USP and 15 mEq of sodium. (A heaping teaspoon may contain as much as 10 to 12 g of Sodium Polystyrene Sulfonate USP). Since the in vivo efficiency of sodium-potassium exchange resins is approximately 33 percent, each one 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 25 to 50 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 must be administered with warm emulsion (at body temperature) in 100 mL of aqueous vehicle. The emulsion should be agitated 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 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 hips are raised on pillows or a knee-shoulder 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 a nonsodium containing solution at body temperature in order to remove the resin. Two quarts of flushing solution may be necessary. The return is 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 administered.

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

Sodium Polystyrene Sulfonate USP should not be heated for to do so may alter the exchange properties of the resin.

HOW SUPPLIED

Sodium Polystyrene Sulfonate USP is available as a light brown to brown finely ground powder in jars of 1 pound (454 g), NDC 46287-012-16. Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F). [See USP Controlled Room Temperature].

SODIUM POLYSTYRENE SULFONATE FOR SUSPENSION

Cation-Exchange Resin

CMP Pharma, Inc.

DESCRIPTION

Sodium Polystyrene Sulfonate USP is a benzenediethenyl polymer of ethenylbenzene, sulfonated, sodium salt and has the following structural formula:

\[
\text{C}_8\text{H}_7\text{SO}_3^+\text{Na}^+\text{CH}_2\text{CH}_2\text{O}^\text{vivo}
\]

The drug is a light brown to brown finely ground, powdered form of sodium polystyrene saponate, a cation-exchange resin prepared 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 mg (4.1 mEq) per gram of the drug. It may 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 salt is 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 unpredictably variable. 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.

INDICATION AND USAGE

Sodium Polystyrene Sulfonate USP is indicated for the treatment of hyperkalemia.

CONTRAINDICATIONS

Sodium Polystyrene Sulfonate USP is contraindicated in the following conditions: patients with hypokalemia, patients with a history of hyperkalemia associated with states of rapid tissue breakdown (e.g., burns and renal failure) or hyperkalemia associated with tissue breakdown from severe disease or surgery, hypokalemic patients in whom sufficient and failure and. Concomitant administration of sorbitol is not recommended (see PRECAUTIONS, Drug Interactions). Use in patients who have normal bowel function. Avoid 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 hyperkalemia associated with tissue breakdown, inflammatory bowel disease, ischemic colitis, vascular intestinal atresia, ileal obstruction).

• Discontinue use in patients who develop constipation.

Alternative Therapy in Severe Hyperkalemia

Since effective lowering of serum potassium with Sodium Polystyrene Sulfonate USP may take hours to days, treatment with this drug alone may be insufficient to rapidly correct severe hyperkalemia associated with cases of rapid tissue breakdown (e.g., burns and renal failure) or hyperkalemia associated with tissue breakdown from severe disease or surgery. The drug may be used to delay the need for dialysis or plasmapheresis, or to initiate dialysis or plasmapheresis for cases in which severe hyperkalemia can potentially be life-threatening. The drug may be used to decrease serum potassium levels to an intermediate level that allows the administration of dialysis or other therapies.
Hypokalemia
Serious hypokalemia may occur from therapy with Sodium Polystyrene Sulfonate USP. 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 treat- ment with Sodium Polystyrene Sulfonate USP 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 clini- cal signs of severe hypokalemia include a pat- tern of variable confusion and delayed thought processes.

Electrocardiographically, severe hypokalemia is often associated with a lengthened Q-T interval, widespread flattening or inversion of the T wave, and prominent U waves. Also, cardiac arrhyth- mias may occur, such as premature atrial, nod- al, and ventricular tachycardias, and supraventricular and ventricular tachycardias. The toxic effects of digitals are likely to be exaggerated. Marked hypokalemia can also be manifested by severe muscle weakness, at times extending into frank paralysis.

Electrolyte Disturbances
Large doses in elderly individuals may cause systemic alkalosis, as magnesium hydroxide and aluminum carbonate. Magnesium hydroxide should not be administered with Sodium Polystyrene Sulfonate USP. One case of grand mal convulsion has been reported in a patient with chronic hypocalcemia who was given Sodium Polystyrene Sulfonate USP. One case of grand mal seizure has been reported in a patient with chronic hypocalcemia of renal failure who was given Sodium Polystyrene Sulfonate USP. One case of grand mal seizure has been reported in a patient with chronic hypocalcemia who was given Sodium Polystyrene Sulfonate USP.

Drug Interactions
Antacids
The simultaneous oral administration of Sodium Polystyrene Sulfonate USP with nonabsorbable cation-donating antacids and laxatives may re- duce the resin’s potassium exchange capability. Any nonabsorbable cation-donating antacids and laxatives should be administered with Sodium Polystyrene Sulfonate USP.

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 USP.

Concomitant use of Sorbitol with Sodium Poly- styrene Sulfonate USP has been implicated in cases of intestinal necrosis, which may progress to frank paralysis and/or death. Lowering of serum calcium and magnesium may result in impaction of the resin. Occasionally diarrhea develops. Large doses in elderly individuals may cause systemic alkalosis, as magnesium hydroxide and aluminum carbonate. Magnesium hydroxide should not be administered with Sodium Polystyrene Sulfonate USP.

Ischemic colitis, gastrointestinal tract ulceration, or necrosis which could lead to intestinal perforation; and, Rare cases of acute bronchitis and/or bronchopneumonia associated with inhalation of particles of polystyrene sulfonate.

OVERDOSAGE

Overdose may result in electrolyte distur- bances including hypokalemia, hypocalcemia, and hypermagnesemia. Biochemical distur- bances 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 apnea. Tetrya may develop. The toxic effects of digitals may change may be consistent with hypokalemia or hypocalcemia; cardiac arrest may occur. Appropriate measures should be taken to correct serum electrolytes (potassium, calcium, magnesium), and the resins should be removed from the alimentary tract by appropriate use of laxatives or enemas.

Sorbitol
Concomitant use of Sorbitol with Sodium Poly- styrene Sulfonate USP has been implicated in cases of intestinal necrosis, which may be fatal. Therefore, concomitant use is not recommended. (See WARNINGS.)

Lithium
Sodium Polystyrene Sulfonate USP may de- crease absorption of lithium.

Thyroxine
Sodium Polystyrene Sulfonate USP may de- crease absorption of thyroxine.

Carcinogenesis, Mutagenesis, Impairment of Fertility
Studies have not been performed.

Pregnancy Category C
Animal reproduction studies have not been con- ducted with Sodium Polystyrene Sulfonate USP. It is also not known whether Sodium Polysty- rene Sulfonate USP can cause fetal harm when administered to a pregnant woman or can af- fect reproduction or fertility. Sodium Polystyrene Sulfonate USP 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 USP is ad- ministered to a nursing woman.

Pediatric Use
The effectiveness of Sodium Polystyrene Sul- fonate USP in pediatric patients has not been established. In neonates, Sodium Polystyrene Sulfonate USP should not be given by the oral route. In both children and adults, use of Sodium Polystyrene Sulfonate USP should be observed with rectal administra- tion, as excessive dosage or inadequate dilution could result in impaction of the resin.

Due to the risk of digestive hemorrhage or in- testinal necrosis, particular care should be ob- served in premature infants or low birth weight infants.

ADVERSE REACTIONS
Sodium Polystyrene Sulfonate USP may cause some degree of gastric irritation. Anorexia, nausea, vomiting, and constipation may occur, especially if high doses are used. As with other resin adsorbents in high doses, hypocalcemia; cardiac arrhythmias may occur. A sign of hypocalcemia, and significant sodium retention, and their re- lated clinical manifestations, may occur (see WARNINGS). Occasionally diarrhea develops. Large doses in elderly individuals may cause systemic alkalosis, as magnesium hydroxide and aluminum carbonate. Magnesium hydroxide should not be administered with Sodium Polystyrene Sulfonate USP. It is also not known whether Sodium Polystyrene Sulfonate USP can cause fetal harm when administered to a pregnant woman or can affect reproduction or fertility. Sodium Polystyrene Sulfonate USP should be given to a pregnant woman only if clearly needed.

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