Sodium Polystyrene Sulfonate Suspension, USP
Sorbitol Free

The only marketed suspension that does not contain sorbitol.

<table>
<thead>
<tr>
<th>Strength</th>
<th>Size</th>
<th>NDC</th>
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<tbody>
<tr>
<td>15g/60mL</td>
<td>480 mL (One Pint)</td>
<td>0574-2003-16</td>
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<tr>
<td>15g/60mL</td>
<td>60 mL (2 fl oz)</td>
<td>0574-2003-02</td>
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Sodium Polystyrene Sulfonate Suspension, USP

Sorbitol Free

Rx only

DESCRIPTION
Sodium Polystyrene Sulfonate Suspension, USP, can be administered orally or in an enema. It is a raspberry-flavored suspension containing 15 grams of cation-exchange resin (sodium polystyrene sulfonate, USP); 0.12 ml (0.2%) of alcohol per 60 ml of suspension. Also contains: purified water, propylene glycol, magnesium aluminum silicate, xanthan gum, sodium saccharin, citric acid, methylparaben, propylparaben, and flavor.

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

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

The sodium content of the suspension is 1500 mg (60 mEq) per 60 ml. It is a brown, slightly viscous suspension with an in-vitro exchange capacity of approximately 3.1 mEq (in-vivo approximately 1 mEq) of potassium per 4 ml (1gram) of suspension. 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 that does the small intestine. The efficiency of this process is limited and unpredictable variable. It commonly approximates the order of 33%, 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 Suspension, USP, is indicated for the treatment of hyperkalemia.

CONTRAINdications
Sodium Polystyrene Sulfonate Suspension, USP, is contraindicated in the following conditions: patients with hyperkalemia, including a history of hypersensitivity to polystyrene sulfonate resins, obstructive bowel disease, oral or rectal administration in neonates (particularly in pre-mature infants), and in any post-operative patient until normal bowel function resumes (see PRECAUTIONS).

WARNINGS
Alternative Therapy in Severe Hyperkalemia
Since the effective lowering of serum potassium with sodium polystyrene sulfonate 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 renal failure) or hyperkalemia so marked as to constitute a medical emergency. Therefore, other definitive measures, including dialysis, should always be considered and may be imperative.

Hyperkalemia
Serious potassium deficiency can occur from sodium polystyrene sulfonate therapy. The effect must be carefully controlled by frequent serum potassium determinations within each 24 hour period. Since extracellular potassium deficiency is not always reflected by serum potassium levels, the level at which treatment with sodium polystyrene sulfonate should be discontinued must be determined individually for each patient. Important aids in making this determination are the patient's clinical condition and the electrocardiogram. Early electrocardiographic signs of severe hyperkalemia include a pattern of irregular confusion and delayed thought processes.

Electrocardiographically, severe hyperkalemia is often associated with a lengthened Q-T interval, widening, flattening, or inversion of the T wave, and prominent U waves. Also, cardiac arrhythmias may occur, such as premature atrial, nodal, and ventricular contractions, and supraventricular and ventricular tachycardias. The toxic effects of digitalis are likely to be exaggerated. Marked hyperkalemia 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 calcium, magnesium, and sodium may be also 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 hypocalcemia 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.

Digitalis
The toxic effects of digitalis on the heart, especially various ventricular arrhythmias and A-V nodal dissociation, are likely to be exaggerated by hypokalemia, even in the face of serum digoxin concentrations in the "normal range" (see WARNINGS).

Sorbitol
Concomitant use of sorbitol with Sodium Polystyrene Sulfonate Suspension, USP is not recommended.

Lithium
Sodium Polystyrene Sulfonate Suspension, USP may decrease absorption of lithium.

Thyroxine
Sodium Polystyrene Sulfonate Suspension, USP 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 Suspension, USP in pediatric patients has not been established. The use of Sodium Polystyrene Sulfonate Suspension, USP is contraindicated in neonates and especially in premature infants. In children, particular care should be observed with rectal administration. In adult patients, it is possible that the sodium polystyrene suspension would be in a retention enema until no concretion is present. Elimination of the enema may require an interval of 12 hours or more. The sodium polystyrene suspension would result in impaction of the resin. Precautions should be taken to ensure the use of adequate volumes of sodium-free cleansing enemas after rectal administration.

ADVERSE REACTIONS
Sodium Polystyrene Sulfonate Suspension, USP, may cause some degree of gastric irritation. Anorexia, nausea, vomiting, and constipation may occur especially if high doses are given. Also, hypokalemia, hypocalcemia, 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 colonic 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 concretions (bezoars) following oral administration;
- 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
Biochemical disturbances resulting from overdose may give rise to clinical signs and symptoms of hypokalemia, including: irritability, confusion, delayed thought processes, muscle weakness, decreased hypotension, which may progress to frank paralysis and/or apnea. Electrocardiographic changes may be consistent with hypokalemia or hyperkalemia; cardiac arrhythmias may occur. Appropriate measures should be taken to correct serum electrolytes (potassium, calcium), and the resin should be removed from the alimentary tract by appropriate use of laxatives or enemas.

DOSAGE AND ADMINISTRATION
The average adult daily dose is 15 g (60 ml) to 60 g (240 ml) of suspension. This is best provided by administering 15 g (60 ml) of Sodium Polystyrene Sulfonate Suspension, USP one to four times a day with 60 ml of Sodium Polystyrene Sulfonate Suspension, USP (optimum 150 ml) up to 540 ml (60 mEq of sodium. Since the in-vivo efficiency of sodium-potassium exchange resins is approximately 33%, 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.

Sodium Polystyrene Sulfonate Suspension, USP, may be introduced into the stomach through a nasogastric tube, and, if desired, given with a diet appropriate for a patient in renal failure.

Sodium Polystyrene Sulfonate Suspension, USP, may also be given, although with less effective results, as an enema consisting (for adults) of 30 g (120 ml) to 50 g (200 ml) every six hours. 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 10 cm, with the tip well into the sigmoid colon, and taped into place. The suspension is introduced at body temperature by gravity. The suspension is flushed with 50 or 100 ml of fluid, following which the tube is clamped and left in place. If back leakage occurs, the enema is stopped and the tube is removed. If a three-chest-position suction is taken temporarily. The suspension is kept in the sigmoid colon for several hours, if possible. Then the colon is irrigated with a sodium-free cleansing enema at body temperature in order to remove the enema. Two quarts of fluid 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 the action depend upon the severity and resistance of hypokalemia. Sodium Polystyrene Sulfonate Suspension, USP should not be heated for to do so may alter the exchange properties of the resin.

HOW SUPPLIED
Sodium Polystyrene Sulfonate Suspension, USP is a light brown, raspberry-flavored suspension supplied as follows:

- 480 ml (16 Fluid Ounce) NDC 0574-2003-16
- Unit-Dose 60 ml (2 Fluid Ounce) NDC 0574-2003-02

Dispense in tight container. If repackaging into other containers, store in refrigerator and use within 4 days of packaging.

SHAKE WELL BEFORE USING.

Store at 20° to 25°C (68° to 77°F) (See USP Controlled Room Temperature).

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2201931 (04-11B)