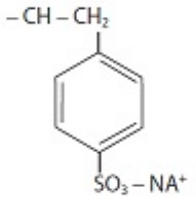
SODIUM POLYSTYRENE SULFONATE- sodium polystyrene sulfonate suspension
Paddock Laboratories, LLC

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, diethenyl-, polymer with ethenylbenzene, sulfonated, sodium salt and has the following structural formula:



The sodium content of the suspension is 1500 mg (65 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 (1 gram) 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 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%, 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 hypokalemia, patients with a history of hypersensitivity to polystyrene sulfonate resins, obstructive bowel disease, oral or rectal administration in neonates (particularly in premature 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.

Hypokalemia

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 intracellular 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 electrocardiogram. Early clinical signs of severe hypokalemia include a pattern of irritable 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. 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 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 calcium 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 hypocalcemia of renal failure who was given sodium polystyrene sulfonate with magnesium hydroxide as a laxative (see **PRECAUTIONS, Drug Interactions**).

Colonic Necrosis

Cases of colonic necrosis 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 prematurity, history of intestinal disease or surgery, hypovolemia, and renal insufficiency and failure. Concomitant administration of sorbitol is not recommended (see **PRECAUTIONS, Drug Interactions**).

PRECAUTIONS

Caution is advised when sodium polystyrene sulfonate is administered to patients who cannot tolerate even a small increase in sodium loads (i.e., severe congestive heart failure, severe hypertension, or marked edema). In such instances, compensatory restriction of sodium intake from other sources may be indicated.

Caution is advised when Sodium Polystyrene Sulfonate Suspension, USP is administered to patients with end stage diabetic renal disease.

Sodium Polystyrene Sulfonate Suspension, USP should not be administered to patients following surgery until normal bowel function resumes.

Precautions should be taken to ensure the use of adequate volumes of sodium-free cleansing enemas after rectal administration.

In the event of clinically significant constipation, treatment with Sodium Polystyrene Sulfonate Suspension, USP should be discontinued until normal bowel motion is resumed. Magnesium-containing laxatives should not be used (see **PRECAUTIONS, Drug Interactions**).

Drug Interactions

Antacids

The simultaneous oral 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 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, as excessive dosage or inadequate dilution could 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 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.

Electrocardiographic changes may be consistent with hypokalemia or hypercalcemia; 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 daily adult 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 daily. Each 60 mL of Sodium Polystyrene Sulfonate Suspension, USP contains 1500 mg (65 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 plastic 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 20 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 hips are elevated on pillows or a knee-chest position 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 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 hyperkalemia.

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:

473 mL (16 Fluid Ounce) NDC 0574-**2003**-16

Unit-Dose 60 mL (2 Fluid Ounce) NDC 0574-**2003**-02

Dispense in tight container, as defined in the USP. If repackaging into other containers, store in refrigerator and use within 14 days of packaging.

SHAKE WELL BEFORE USING.

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

Manufactured By

Perrigo®

Minneapolis, MN 55427

2201910 7S200 RC J1

Rev 10-13 A

Package/Label Display Panel – 60 mL

Rx Only

NDC 0574-**2003**-02

Sodium Polystyrene Sulfonate Suspension, USP

15 g/60 mL

Does not contain Sorbitol

Dispense in tight container.

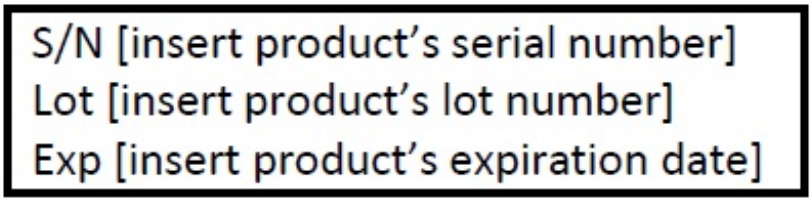
SHAKE WELL BEFORE USING

Protect from freezing and from excessive heat.

FOR ORAL OR RECTAL USE

60 mL (2 fl oz)

The following image is a placeholder representing the product identifier that is either affixed or imprinted on the drug package label during the packaging operation.



Package/Label Display Panel – 473 mL

Rx Only

NDC 0574-**2003**-16

Sodium Polystyrene Sulfonate Suspension, USP

15 g/60 mL

Does not contain Sorbitol

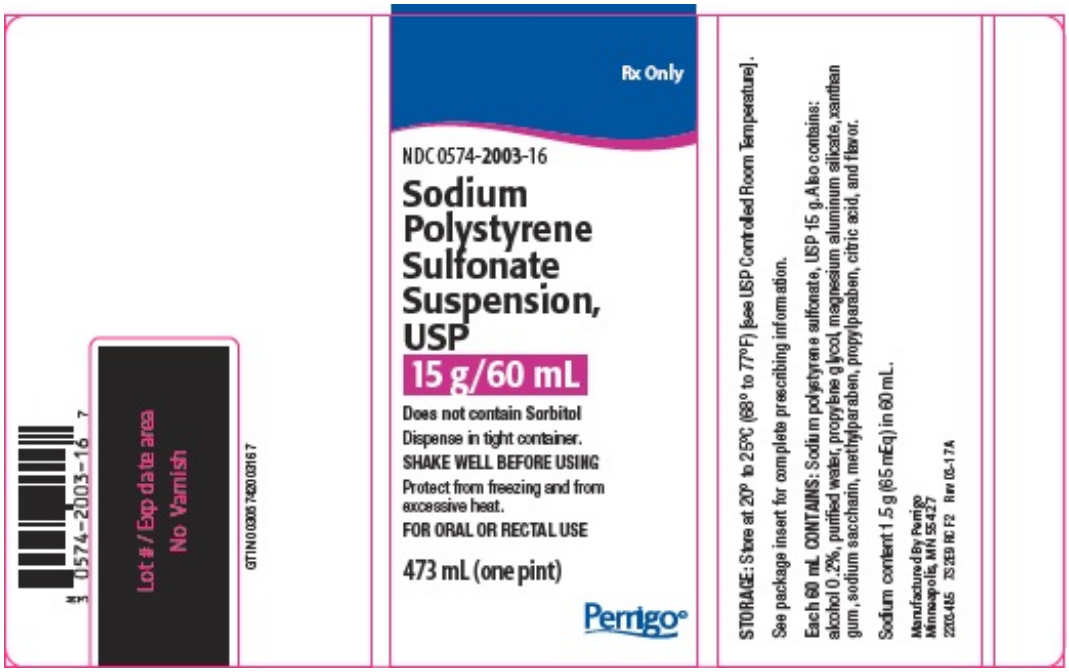
Dispense in tight container.

SHAKE WELL BEFORE USING

Protect from freezing and from excessive heat.

FOR ORAL OR RECTAL USE

473 mL (one pint)



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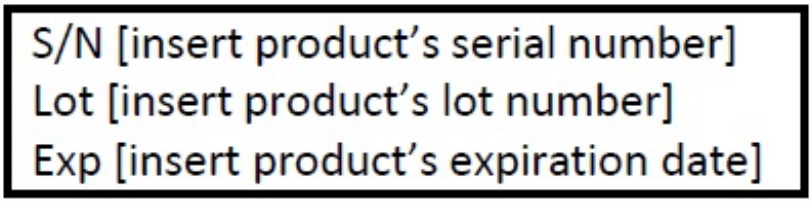

SODIUM POLYSTYRENE SULFONATE

sodium polystyrene sulfonate suspension

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0574-2003
Route of Administration	ORAL, RECTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Sodium Polystyrene Sulfonate (UNII: 1699G8679Z) (POLYSTYRENE SULFONIC ACID - UNII:70KO0R01RY)	Sodium Polystyrene Sulfonate	15 g in 60 mL

Inactive Ingredients	
Ingredient Name	**Strength**
water (UNII: 059QF0KO0R)	
propylene glycol (UNII: 6DC9Q167V3)	
magnesium aluminum silicate (UNII: 6M3P64V0NC)	

xanthan gum (UNII: TTV12P4NEE)	
saccharin sodium (UNII: SB8ZUX40TY)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
methylparaben (UNII: A2I8C7HI9T)	
propylparaben (UNII: Z8IX2SC1OH)	
ALCOHOL (UNII: 3K9958V90M)	

Product Characteristics

Color	BROWN	**Score**	
Shape		**Size**	
Flavor	RASPBERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0574-2003-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/02/2014	
2	NDC:0574-2003-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/14/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090590	09/21/2011	

Labeler - Paddock Laboratories, LLC (967694121)

Revised: 11/2018 Paddock Laboratories, LLC