SODIUM POLYSTYRENE SULFONATE FOR SUSPENSION

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use SODIUM POLYSTYRENE SULFONATE FOR SUSPENSION safely and effectively. See full prescribing information for details.

INDICATIONS AND USAGE
SODIUM POLYSTYRENE SULFONATE FOR SUSPENSION is indicated for the treatment of hyperkalemia.

DOSAGE AND ADMINISTRATION

Oral: The average total daily adult dose of SODIUM POLYSTYRENE SULFONATE FOR SUSPENSION is 15 g to 60 g, administered as a 15-g dose (four level teaspoons), one to four times daily. Lower doses may be used in patients with less severe or unstable hyperkalemia. The intensity and duration of therapy depend upon the severity and resistance of hyperkalemia.

Rectal: The average total daily adult rectal dose of SODIUM POLYSTYRENE SULFONATE FOR SUSPENSION is 15 g to 60 g, administered as a 15-g dose (four level teaspoons), one to four times daily.

CONTRAINDICATIONS
SODIUM POLYSTYRENE SULFONATE FOR SUSPENSION is contraindicated in patients with

- Neonates with reduced gut motility
- Obstructive bowel disease
- Hypersensitivity to polystyrene sulfonate (4)

Limitation of Use: SODIUM POLYSTYRENE SULFONATE FOR SUSPENSION safely and effectively. See full prescribing information for details.

WARNINGS AND PRECAUTIONS

- Intestinal Necrosis: cases of intestinal necrosis and other serious gastrointestinal events (such as perforation) have been reported in association with SODIUM POLYSTYRENE SULFONATE FOR SUSPENSION 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 prerenal, history of intestinal disorders as surgery, hypokalemia, and renal insufficiency among others.

Other reports of gastrointestinal adverse events (perforation, inflammatory bowel disease, ischemic colitis, failure) were reported. Concomitant administration of sorbitol is not recommended.

- Fluid Overload in Patient Sensitive to High Sodium Intake: Monitor patients who are sensitive to sodium intake for signs of fluid overload.

- Electrolyte Disturbances: Severe hypokalemia can occur. (5.2). Monitor serum potassium during therapy because severe hypokalemia may occur.

- Intestinal Necrosis: Monitor patients who are sensitive to the risk of intestinal necrosis and is not recommended.

DRUG INTERACTIONS

- Take other commonly administered medications at least 3 hours before or 3 hours after SODIUM POLYSTYRENE SULFONATE FOR SUSPENSION use. See full prescribing information for details.

- Cation-Donating Antacids: may reduce the resin's potassium exchange capability and is not recommended.

- Take other orally administered drugs at least 3 hours before or 3 hours after SODIUM POLYSTYRENE SULFONATE FOR SUSPENSION 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 prerenal, history of intestinal disorders as surgery, hypokalemia, and renal insufficiency among others.

- Avoid use in patients who are at risk for developing constipation or impaction (including those with gastroparesis) or in patients who have not had a bowel movement in at least 3 days.

- Avoid use in patients who have normal bowel function. Avoid use in patients who have not had a bowel movement in at least 3 days.

- Do not administer sorbitol if the patient has a history of intolerance of sorbitol. Risk factors for gastrointestinal adverse events were present in many of the cases including prerenal, history of intestinal disorders as surgery, hypokalemia, and renal insufficiency among others.

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[see Dosage]

STYRENE SULFONATE FOR SUSPENSION by at least 3 hours (before or after)

Advise patients who are taking other oral medication to separate the dosing of SODIUM POLYSTYRENE SULFONATE FOR SUSPENSION from other oral medication taken at least 3 hours before or after SODIUM POLYSTYRENE SULFONATE FOR SUSPENSION.

17 PATIENT COUNSELING INFORMATION

[see USP]

[One mL (15 g) of SODIUM POLYSTYRENE SULFONATE FOR SUSPENSION contains 1500 mg of resin (approximately 1 mEq of potassium per gram). The sodium content is approximately 170 mg per mL (170 mg per 15 g).]

Clinical Pharmacology

12.2 Pharmacodynamics

The effective lowering of serum potassium with SODIUM POLYSTYRENE SULFONATE FOR SUSPENSION primarily occurs when the resin is administered. Administer SODIUM POLYSTYRENE SULFONATE FOR SUSPENSION to other oral medications at least 3 hours before or after other oral medications. Patients with gastroparesis may require a 4-hour separation. Monitor for renal response and/or blood levels when possible.

12.1 Mechanism of Action

SODIUM POLYSTYRENE SULFONATE FOR SUSPENSION increases fecal potassium excretion, reduces the concentration of free potassium in the gastrointestinal lumen, resulting in a reduction in systemic alkalosis. Binding of potassium reduces the excitation and propagation of propagated action potentials within excitable tissues. The practical exchange ratio is 1 mEq K per 1 gram of resin. The resin is expected to bind potassium at the practical exchange ratio of 1 mEq potassium per 1 gram of resin.

6 USE IN SPECIFIC POPULATIONS

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8.1 Pregnancy

8.2 Lactation

SODIUM POLYSTYRENE SULFONATE FOR SUSPENSION is not absorbed systemically following oral or rectal administration and is not expected to result in toxic or systemic effects.

10 OVERDOSAGE

Cases of acute bronchitis or bronchopneumonia caused by inhalation of sodium polystyrene sulfonate particles have been reported. Patients with impaired gag reflex, altered level of consciousness, or patients prone to regurgitation may be at increased risk. Administer SODIUM POLYSTYRENE SULFONATE FOR SUSPENSION with the patient in an upright position.

Drug Interactions

5.3 Fluid Overload in Patients Sensitive to High Sodium Intake

SODIUM POLYSTYRENE SULFONATE FOR SUSPENSION is a non-absorbed, cation exchange polymer that contains a sodium counterion. The sodium content is approximately 170 mg per mL (170 mg per 15 g). The resin is expected to bind potassium at the practical exchange ratio of 1 mEq potassium per 1 gram of resin. The sodium content is approximately 170 mg per mL (170 mg per 15 g).

6 ADVERSE REACTIONS

The following adverse reactions are discussed elsewhere in the labeling:

- Drug Interactions
- Gastrointestinal
- Hypokalemic-Related
- Hypocalcemic-Related
- Metabolic
- Other

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The drug is a light brown to brown, finely ground powder of sodium polystyrene sulfonate, a cation exchange resin prepared in the sodium phase with an exchange capacity when taken close to the time SODIUM POLYSTYRENE SULFONATE FOR SUSPENSION with nonabsorbable cation-donating antacids and laxatives may reduce the resin’s potassium excretion. The following adverse reactions are discussed elsewhere in the labeling:

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