

Data Sheet

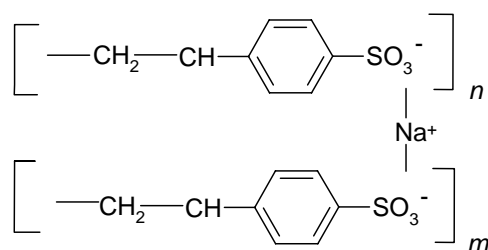
RESONIUM A

Name of the Medicine

Non-proprietary Name

Sodium polystyrene sulfonate

Chemical Structure



CAS Number

28210-41-5 [9003-59-2]

Description

Resonium A contains 99.93% sodium polystyrene sulfonate as a finely ground powder. The sodium content is approximately 4.1mmol (100 mg) per gram of Resonium A.

Resonium A also contains saccharin sodium and vanillin.

Pharmacology

Class

Sodium polystyrene sulfonate is a cation exchange resin prepared in the sodium phase.

Site and Mode of Action

It has an *in vitro* exchange capacity of approximately 3.1 mmol of potassium per gram of resin. However, *in vivo* the actual amount of potassium bound is closer to 1 mmol of potassium per gram.

Pharmacokinetics

Absorption

Sodium polystyrene sulfonate is not absorbed from the gastrointestinal tract.

Distribution

Sodium polystyrene sulfonate removes potassium from the body by exchanging it within the gut for sodium.

Excretion

For the most part, this action occurs in the large intestine, which excretes potassium to a greater degree than does the small intestine.

The efficiency of potassium exchange is unpredictable and variable.

Indications

Treatment of hyperkalaemia.

Contraindications

- History of hypersensitivity to polystyrene sulfonate resins.
- Serum potassium levels less than 5mmol/L
- Obstructive bowel disease
- Resonium A should not be administered **orally** to neonates and is contraindicated in neonates with reduced gut motility (eg. post-operatively or drug induced)

Precautions

Serious potassium deficiency can result from Resonium A therapy. It is imperative to determine serum potassium levels at least daily and more frequently when indicated, especially in patients on digoxin. Therapy should be discontinued when serum potassium falls below 5mmol/L.

Caution is advised when Resonium A is administered to patients who cannot tolerate even a small increase in sodium loads (ie severe congestive heart failure, severe hypertension, renal damage or marked oedema). In such instances, adequate clinical and biochemical control is essential.

Like all cation-exchange resins, Resonium A 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 Resonium A should be monitored for all applicable electrolyte disturbances.

In the event of clinically significant constipation, treatment with the resin should be discontinued until normal bowel habit is resumed. Magnesium containing laxatives should not be used (see **Interactions with Other Medicines**).

With oral administration, care should be taken to avoid aspiration, which may lead to bronchopulmonary complications.

Concomitant use of sorbitol with sodium polystyrene sulfonate is not recommended since cases of intestinal necrosis, which may be fatal, have been reported (see Interactions with Other Medicines and **ADVERSE EFFECTS**). Since effective lowering of serum potassium with Resonium A may take hours to days, treatment with this drug alone may be insufficient to rapidly correct severe hyperkalaemia, often associated with states of rapid tissue breakdown eg burns or trauma. In such instances, some form of dialysis may be imperative. If hyperkalaemia is so marked as to constitute a medical emergency, immediate treatment with intravenous glucose and insulin or intravenous sodium bicarbonate may be necessary as a temporary measure to lower serum potassium while other long-term potassium lowering therapy is being prepared.

Paediatric Use

In neonates, Resonium A should not be given by the oral route.

In 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 haemorrhage or colic necrosis, particular care should be observed in premature infants or low birth weight infants.

Pregnancy and Lactation

No data are available regarding the use of polystyrene sulfonate resins in pregnancy and lactation. The administration of Resonium A in pregnancy and during breast-feeding therefore, is not advised unless, in the opinion of the physician, the potential benefits outweigh any potential risks.

Interactions with Other Medicines

- Cation donating agents may reduce the effectiveness of the resin in binding potassium.
- Non-absorbable cation containing antacids and laxatives such as magnesium hydroxide and concomitant oral use of cation exchange resins has been reported to cause systemic alkalosis.
- Aluminium hydroxide: intestinal obstruction due to concretions of aluminium hydroxide has been reported when aluminium hydroxide was combined with the resin.
- Digoxin: the toxic effects of digoxin on the heart, especially various ventricular arrhythmias and AV nodal depression are likely to be exaggerated if hypokalaemia is allowed to develop.
- Lithium: Possible decrease of lithium absorption.
- Thyroxine: Possible decrease of thyroxine absorption.
- Concomitant use of sorbitol with sodium polystyrene sulfonate is not recommended due to cases of intestinal necrosis, which may be fatal (see **PRECAUTIONS** and **ADVERSE EFFECTS**).

Adverse Effects

In accordance with its pharmacological actions, the resin may give rise to sodium retention, hypokalaemia and hypocalcaemia and their related clinical manifestations (see **PRECAUTIONS**).

Cases of hypomagnesemia, have been reported.

Gastric irritation, anorexia, constipation, nausea, vomiting and occasionally diarrhoea may also occur. Large doses in elderly individuals may cause faecal impaction. These effects may be obviated through usage of the resin in enemas. Intestinal obstruction has also been reported rarely.

Faecal impaction following rectal administration in children, and gastrointestinal concretions following oral administration to neonates have been reported.

Some cases of acute bronchitis and/or bronchopneumonia associated with inhalation of particles of sodium polystyrene sulfonate have been described.

Ischemic colitis, gastrointestinal tract ulceration or necrosis which could lead to intestinal perforation have been reported following administration of sodium polystyrene sulfonate. (see also **PRECAUTIONS**).

Intestinal necrosis has been reported with concomitant use of sorbitol (see Interactions with Other Medicines and **PRECAUTIONS**).

Dosage and Administration

Resonium A is for oral or rectal administration only. The dosage recommendations detailed below are a guide only; the precise requirements should be decided on a basis of regular clinical and serum electrolyte determinations.

Adults

Oral

15 g three to four times daily. Each dose should be given as a suspension in a small amount of water or, for greater palatability, in syrup (but not fruit juices, which contain potassium), in the ratio of 3-4 mL per gram of resin.

Rectal

In cases where vomiting or upper gastrointestinal problems, including paralytic ileus, may make oral administration difficult, Resonium A may be given rectally in a suspension of 30 g to 50 g resin in 150 mL water or 10% dextrose in water, given as a daily retention enema. In the initial stages,

administration by this route as well as orally may help to achieve a more rapid lowering of the serum potassium level.

The enema should if possible be retained for at least nine hours, following which, the colon should be irrigated to remove the resin. If both routes are used at first, it is probably unnecessary to continue rectal administration once the oral resin has reached the rectum.

Infants and Children

Oral

Lower doses should be employed using, as a guide, a rate of 1 mmol potassium per gram of resin as the basis for calculation. An appropriate initial dose is 1 g/kg body weight daily in divided doses, in acute hyperkalaemia. For maintenance therapy, dosage may be reduced to 0.5 g/kg body weight daily in divided doses. Each dose should be given as a suspension in a small amount of water or, for greater palatability, in syrup (but not fruit juices, which contain potassium), in the ratio of 3-4 mL per gram of resin.

Rectal

When the resin cannot be given by mouth, it may be given rectally using a dose at least as great as that which would have been given orally, diluted in the same ratio as described for adults. Following retention of the enema, the colon should be irrigated to ensure adequate removal of the resin.

In the initial stages, administration by this route as well as orally may help to achieve a more rapid lowering of the serum potassium level. If both routes are used at first, it is probably unnecessary to continue rectal administration once the oral resin has reached the rectum.

Overdosage

Biochemical disturbances resulting from overdosage may give rise to clinical signs and symptoms of hypokalaemia, including irritability, confusion, delayed thought processes, muscle weakness, hyporeflexia or paralysis. Apnea may be a serious consequence of this progression. ECG changes may be consistent with hypokalaemia; cardiac arrhythmia may occur. Hypocalcaemic tetany may occur. Appropriate measures should be taken to monitor and correct serum electrolytes, and the resin should be removed from the alimentary tract by appropriate use of laxatives or enemas.

Contact the Poisons Information Centre for advice on management of overdosage.

Presentation and Storage Conditions

Powder 454 g in a tub.

Store below 30°C.

Suspensions of the resin should be freshly prepared and not stored beyond 24 hours.

Medicine Classification

Prescription Medicine.

Name and Address of the Sponsor

sanofi-aventis new zealand limited
Level 8, James & Wells Tower
56 Cawley Street
Ellerslie
Auckland
Phone: (09) 580 1810

Date of Preparation

5 August 2010