AUSTRALIAN PRODUCT INFORMATION – RESONIUM A (sodium polystyrene sulfonate) POWDER

1 NAME OF THE MEDICINE

Sodium polystyrene sulfonate.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Resonium A contains 99.93% sodium polystyrene sulfonate, saccharin sodium and vanillin.

The sodium content is approximately 4.1mmol (100 mg) per gram of Resonium A.

Excipients with known effect: saccharin.

3 PHARMACEUTICAL FORM

Buff coloured powder.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Treatment of hyperkalaemia.

4.2 DOSE AND METHOD OF ADMINISTRATION

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

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.

Administer at least 3 hours before or 3 hours after other oral medications. For patients with gastroparesis, a 6-hour separation should be considered (see Section 4.4 - Special Warnings and Precautions for Use and Section 4.5 - Interactions with Other Medicines and Other Forms of Interactions).

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.

4.3 CONTRAINDICATIONS

History of hypersensitivity to polystyrene sulfonate resins.

Serum potassium levels less than 5 mmol/L.

Obstructive bowel disease.

Resonium A should not be administered orally to neonates and is contraindicated in neonates with reduced gut motility (e.g. post-operatively or drug induced).

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Due to the risk of severe gastrointestinal disorders the use of polystyrene sulfonate is not

recommended in patients with compromised gastrointestinal motility (including immediate post-surgery or drug-induced).

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 5 mmol/L.

Caution is advised when Resonium A is administered to patients in whom an increase in sodium load may be detrimental (i.e. 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 Section 4.5 - Interactions with Other Medicines and Other Forms of Interactions).

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

Gastrointestinal stenosis, intestinal ischaemia and its complications (necrosis and perforation), some of them fatal, were reported in patients treated with polystyrene sulfonate alone or in combination with sorbitol. Concomitant use of sorbitol with sodium polystyrene sulfonate is not recommended (see Section 4.5 - Interactions with Other Medicines and Other Forms of Interactions and Section 4.8 - Adverse Effects (Undesirable 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.

Binding to other orally administered medications

Resonium A may bind to orally administered medications, which could decrease their gastrointestinal absorption and efficacy. Avoid co-administration of Resonium A with other orally administered medications. Administer Resonium A at least 3 hours before or 3 hours after other oral medications. For patients with gastroparesis, a 6-hour separation should be considered (see Section 4.4 - Special Warnings and Precautions for Use and Section 4.5 - Interactions with Other Medicines and Other Forms of Interactions).

Use in the elderly

No data available.

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

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Concomitant use not recommended

Resonium A has the potential to bind to other orally administered medications. Binding of Resonium A to other oral medications could cause decrease in their gastrointestinal absorption and efficacy. Dosing separation of Resonium A from other orally administered medications is recommended (see Section 4.2 - Dose and Method of Administration).

Concomitant use of sorbitol with sodium polystyrene sulfonate is not recommended due to cases of intestinal necrosis, and other serious gastrointestinal adverse reactions, which may be fatal (see Section 4.4 - Special Warnings and Precautions for Use and Section 4.8 - Adverse Effects (Undesirable Effects)).

To be used with caution

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/dissociation are likely to be exaggerated if hypokalaemia is allowed to develop.

Lithium: Possible decrease of lithium absorption.

Thyroxine: Possible decrease of thyroxine absorption.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available.

Use in pregnancy

Category B2.

No data are available regarding the use of polystyrene sulfonate resins in pregnancy. The administration of Resonium A in pregnancy is not advised unless the potential benefits outweigh any potential risks.

Use in lactation

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

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Metabolism and nutrition disorders

In accordance with its pharmacological actions, the resin may give rise to sodium retention, hypokalaemia and hypocalcaemia and their related clinical manifestations (see Section 4.4 - Special Warnings and Precautions for Use). Cases of hypomagnesemia, have been reported.

Respiratory, thoracic and mediastinal disorders

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

Gastrointestinal disorders

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. Faecal impaction following rectal administration, particularly in children, and gastrointestinal concretions (bezoars) following oral administration have been reported.

Gastrointestinal stenosis and intestinal obstruction have also been reported possibly due to co-existing pathology or inadequate dilution of the resin.

Gastrointestinal ischemia, ischemic colitis, gastrointestinal tract ulceration or necrosis which could lead to intestinal perforation have been reported following administration of sodium polystyrene sulfonate, which is sometimes fatal (see Section 4.4 - Special Warnings and Precautions for Use).

Reporting suspected adverse reactions

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

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. Apnoea 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.

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Pharmacotherapeutic group: Drugs for treatment of hyperkalemia and hyperphosphatemia, ATC code: V03AE01

Mechanism 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.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

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.

Metabolism

No data available.

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.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Refer to Section 2 - Qualitative and Quantitative Description.

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 30°C. Store in a dry place.

Suspensions of the resin should be freshly prepared and not stored beyond 24 hours. Once reconstituted, Resonium A is a cream to light brown coloured suspension in which small white particulates may remain visible.

6.5 NATURE AND CONTENTS OF CONTAINER

High density polyethylene (HDPE) bottle with cap composed of low and density polyethylene (LDPE/HDPE) containing 454 g of sodium polystyrene sulfonate powder and a HDPE dosing spoon.

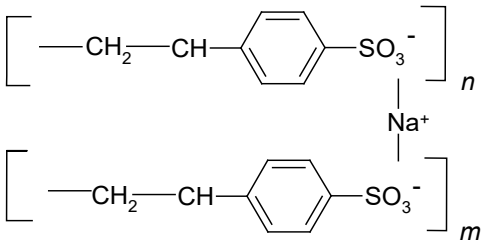
6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

6.7 PHYSICOCHEMICAL PROPERTIES

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

Chemical structure



CAS number

9080-79-9

7 MEDICINE SCHEDULE (POISONS STANDARD)

Schedule 4 (Prescription Only Medicine)

8 SPONSOR

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Macquarie Park NSW 2113
Freecall: 1800 818 806
Email: medinfo.australia@sanofi.com

9 DATE OF FIRST APPROVAL

10 September 1991

10 DATE OF REVISION

23 July 2024

SUMMARY TABLE OF CHANGES

Section Changed	Summary of New Information
4.8, 4.9, 8	New Zealand specific details removed
8	Sponsor details reformatted