

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Resonium A

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains Sodium Polystyrene Sulfonate 99.934% w/w.

Excipient with known effect:

Sodium 1,400 to 1,700 mg per 15g dose (see section 4.4).

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Powder for Oral/Rectal Suspension

Buff coloured powder

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Resonium A is an ion-exchange resin that is recommended for the treatment of hyperkalaemia associated with anuria or severe oliguria. It is also used to treat hyperkalaemia in patients requiring dialysis and in patients on regular haemodialysis or on prolonged peritoneal dialysis.

### 4.2 Posology and method of administration

Posology

The dosage recommendations detailed in this section are a guide only; the precise requirements should be decided on the basis of regular serum electrolyte determinations.

*Adults, including the elderly:*

Oral:

The usual dose is 15g three or four times a day. 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 to 4ml per gram of resin.

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 sections 4.4 & 4.5).

Rectal:

This route should be reserved for the patient who is vomiting or who has upper gastrointestinal tract problems, including paralytic ileus. It may be used simultaneously with the oral route for more rapid initial results or in patients with gastroparesis, who have other orally administered medications that are administered within 6 hours of Resonium A. The resin may be given rectally as a suspension of 30g resin in 150ml of water or 10% dextrose, 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 initially it is probably unnecessary to continue rectal administration once the oral resin has reached the rectum.

#### *Paediatric population*

Oral:

In smaller children and infants correspondingly smaller doses should be employed by using as a guide a rate of 1mEq of potassium per gram of resin as the basis for calculation. An appropriate initial dose is 1g/kg body weight daily in divided doses, in acute hyperkalaemia. Dosage may be reduced to 0.5g/kg of body weight daily in divided doses for maintenance therapy.

The resin is given orally, preferably with a drink (not a fruit squash because of the high potassium content) or a little jam or honey.

Rectal:

When refused by mouth it should 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.

#### *Neonates*

***Resonium A should not be given by the oral route.*** With rectal administration, the minimum effective dosage within the range 0.5g/kg to 1g/kg should be employed diluted as for adults and with adequate irrigation to ensure recovery of the resin.

#### Method of Administration

Resonium A is for oral or rectal administration only.

### **4.3 Contraindications**

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1
- In patients with plasma potassium levels below 5mmol/litre.
- History of hypersensitivity to polystyrene sulfonate resins.
- Obstructive bowel disease.
- Resonium A should not be administered *orally* to neonates and is contraindicated in neonates with reduced gut motility (post-operatively or drug-induced).

#### 4.4 Special warnings and precautions for use

***Binding to other orally administered medications:*** Calcium Resonium may bind to orally administered medications, which could decrease their gastrointestinal absorption and efficacy. Avoid co-administration of Calcium Resonium with other orally administered medications. Administer Calcium Resonium at least 3 hours before or 3 hours after other oral medications. For patients with gastroparesis, a 6-hour separation should be considered (see Sections 4.2 & 4.5).

***Gastrointestinal stenosis and ischaemia:*** Gastrointestinal stenosis, intestinal ischemia 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 calcium polystyrene sulfonate is not recommended (see Section 4.5).

Patients should be advised to seek prompt medical advice in case of newly developed severe abdominal pain, nausea and vomiting, stomach distension and rectal bleeding.

Lesions seen in polystyrene sulfonate-induced gastrointestinal damage may overlap with those seen in inflammatory bowel disease, ischemic colitis, infectious colitis, and microscopic colitis.

***Severe gastrointestinal disorders:*** Due to the risk of severe gastrointestinal disorders (such as bowel obstruction, ischaemia, necrosis or perforation) the use of polystyrene sulfonate is not recommended in patients with compromised gastrointestinal motility (including immediate post-surgery or drug-induced).

***Hypokalaemia:*** The possibility of severe potassium depletion should be considered and adequate clinical and biochemical control is essential during treatment, especially in patients on digitalis. Administration of the resin should be stopped when the serum potassium falls to 5mmol/litre.

***Other electrolyte disturbances:*** Like all cation-exchange resins, calcium polystyrene sulfonate is not totally selective for potassium. Hypomagnesaemia and/or hypercalcaemia may occur. Accordingly, patients should be monitored for all applicable electrolyte disturbances. Serum calcium levels should be estimated at weekly intervals to detect the early development of hypercalcaemia, and the dose of resin adjusted to levels at which hypercalcaemia and hypokalaemia are prevented.

***Other risks:*** In the event of clinically significant constipation, treatment should be discontinued until normal bowel movement has resumed. Magnesium-containing laxatives should not be used (see section 4.5 Interactions).

The patient should be positioned carefully when ingesting the resin, to avoid aspiration, which may lead to bronchopulmonary complications.

**Children and neonates:** In neonates, calcium polystyrene sulfonate should not be given by the oral route. In children and neonates, particular care is needed with rectal administration as excessive dosage or inadequate dilution could result in impaction of the resin. Due to the risk of digestive haemorrhage or colonic necrosis, particular care should be observed in premature infants or low birth weight infants.

**Sodium:** This medicinal product contains less than 1 mmol sodium (23 mg) per 15g powder, that is to say essentially 'sodium free'.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

Orally administered medications: 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 sections 4.2 & 4.4).

##### ***Concomitant use not recommended***

Sorbitol (oral or rectal): 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 Section 4.8 Undesirable effects).

##### ***To be used with caution***

- Cation-donating agents: may reduce the potassium binding effectiveness of Resonium A.
- Non-absorbable cation-donating antacids and laxatives: There have been reports of systemic alkalosis following concurrent administration of cation-exchange resins and non-absorbable cation-donating antacids and laxatives such as magnesium hydroxide and aluminium carbonate.
- Aluminium hydroxide: Intestinal obstruction due to concretions of aluminium hydroxide has been reported when aluminium hydroxide has been combined with the resin.
- Digitalis-like drugs: The toxic effects of digitalis on the heart, especially various ventricular arrhythmias and A-V nodal dissociation, are likely to be exaggerated if hypokalaemia is allowed to develop. (See 4.4 Special warnings and special precautions for use).
- Lithium: Possible decrease of lithium absorption.
- Levothyroxine: Possible decrease of levothyroxine absorption.\

#### **4.6 Fertility, 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.

#### **4.7 Effects on ability to drive and use machines**

There are no specific warnings.

#### **4.8 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 Section 4.9 Overdose).

Cases of hypomagnesaemia have been reported.

##### **Gastrointestinal disorders**

Gastric irritation, anorexia, nausea, vomiting, constipation and occasionally diarrhoea may occur. 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, gastro-intestinal tract ulceration or necrosis, which could lead to intestinal perforation have been reported which is sometimes fatal.

##### **Respiratory, thoracic and mediastinal disorders**

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

##### **Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation 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 via Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for **MHRA Yellow Card in the Google Play or Apple App Store**.

#### **4.9 Overdose**

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

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: drugs for treatment of hyperkalaemia and hyperphosphatemia, ATC code: V03AE01.

Resonium A is a cation exchange resin for the treatment of hyperkalaemia.

### **5.2 Pharmacokinetic properties**

Ion exchange resins with a particle size ranging from 5 - 10 micrometres (as in Resonium A) are not absorbed from the gastro-intestinal tract and are wholly excreted in the faeces.

### **5.3 Preclinical safety data**

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Sodium  
Saccharin  
Vanillin

### **6.2 Incompatibilities**

There are no specific incompatibilities

### **6.3 Shelf life**

60 months

**6.4 Special precautions for storage**

None stated

**6.5 Nature and contents of container**

Supplied in HDPE containers with LDPE tamper evident closures containing 454g Resonium A together with a plastic scoop, which, when filled level, contains approximately 15g.

**6.6 Special precautions for disposal**

Refer to 4.2. Posology and method of administration

**7 MARKETING AUTHORISATION HOLDER**

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PL 04428/0178

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21/08/ 1993 / 18/07/2003

**10 DATE OF REVISION OF THE TEXT**

20/12/2023