RESONIUM-A

Brand of sodium polystyrene sulfonate

COMPOSITION

Resonium A is ground and flavoured sodium polystyrene sulphonate. It is a buff-colored powder with a pleasant vanilla odour and sweet taste. Available in lever-lid H.D.P.E. containers of 454g Resonium A together with a plastic scoop which, when filled level, contains approximately 15g.

CLINICAL PARTICULARS

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.

Posology and method of administration

Resonium A is for oral or rectal administration only.

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. The resin is given by mouth in a little water, or it may be made into a paste with some sweetened vehicle.

Rectal

In cases where vomiting may make oral administration difficult, the resin may be given rectally as a suspension of 30g resin in 100ml 2% methylcellulose 450 BP (medium viscosity) and 100ml water, 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.

Children:

Oral

1g/kg body weight daily in divided doses for 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.

Contraindications

- In patients with plasma potassium levels below 5mmol/litre.
- History of hypersensitivity to polystyrene sulphonate 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).

Special warnings and special precautions for use

Sorbitol: Gastrointestinal stenosis, intestinal ischemia and its complications (necrosis and perforation) may occur in patients treated with polystyrene sulfonate, especially in patients using sorbitol. Therefore, concomitant use of sorbitol with sodium polystyrene sulfonate is not recommended (see section **Interactions** and Und**esirable effects**).

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: Because the resin may bind calcium and magnesium ions, deficiencies of these electrolytes may occur. Accordingly, patients should be monitored for all applicable electrolyte disturbances.

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 Interactions).

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

Children and neonates: In neonates, sodium polystyrene sulphonate 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.

Patients at risk from an increase in sodium load: Care should be taken when administering to patients in whom an increase in sodium load may be detrimental (i.e. congestive heart failure, hypertension, renal damage or oedema). In such cases, calcium polystyrene sulphonate may be used in place of Resonium A.

Interactions with other medicinal products and other forms of interaction

Concomitant use not recommended
Sorbitol (oral or rectal): Concomitant use of sorbitol with sodium polystyrene sulphonate is not recommended due to cases of intestinal necrosis, and other serious gastrointestinal adverse reactions, which may be fatal.

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.
- Thyroxine: Possible decrease of thyroxine absorption.

Pregnancy and lactation

No data are available regarding the use of polystyrene sulphonate 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.

Effects on ability to drive and use machines

There are no specific warnings.

Undesirable effects
In accordance with its pharmacological actions, the resin may give rise to sodium retention, hypokalaemia and hypocalcaemia and their related clinical manifestations (see Warnings and Precautions and Overdosage).

- **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 due to co-existing pathology or inadequate dilution of resin.
Gastrointestinal ischemia, ischemic colitis, gastro-intestinal tract ulceration or necrosis which could lead to intestinal perforation have been reported which is sometimes fatal.
The majority of cases have been reported with concomitant use of sorbitol (see section **Interactions** and Und**esirable effects**).

- **Respiratory disorders**

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

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.

PHARMACOLOGICAL PROPERTIES
Pharmacodynamic properties
Resonium A is a cation exchange resin for the treatment of hyperkalaemia.

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.

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.

List of excipients
Resonium A also contains: saccharin and vanillin.

Special precautions for storage
Store at room temperature in a dry place.

Shelf life
5 years

Manufactured by: Sanofi Winthrop Industrie

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