SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Calcium Resonium 99.934% w/w Powder for Oral/Rectal Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each bottle contains 99.934% w/w of the active substance Calcium Polystyrene Sulfonate.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for Oral/Rectal Suspension

Cream or light brown coloured, fine powder

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Calcium Resonium 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

Calcium Resonium is for oral or rectal administration only.

The dosage recommendations detailed below 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.

Rectal
This route should be reserved for the patient who is vomiting or who has upper gastrointestinal tract problems, including paralytic ileus or it may be used simultaneously with the oral route for more rapid initial results. 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 rapid lowering of the serum potassium level.

The enema should if possible be retained for a least nine hours, then 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
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 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:
Calcium Resonium 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 with adequate irrigation to ensure recovery of the resin.

4.3 Contraindications

- In patients with plasma potassium levels below 5mmol/litre.
- Conditions associated with hypercalcaemia (e.g. hyperparathyroidism, multiple myeloma, sarcoidosis or metastatic carcinoma).
- History of hypersensitivity to polystyrene sulfonate resins.
- Obstructive bowel disease.
- Calcium Resonium should not be administered orally to neonates and is contraindicated in neonates with reduced gut motility (post-operatively or drug-induced).
- Hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings and 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 calcium polystyrene sulfonate is not recommended (see Section 4.5 Interactions and Section 4.8 Undesirable 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: 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.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant use not recommended
Sorbitol (oral or rectal): Concomitant use of Sorbitol with calcium 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 Undesirable effects).

To be used with caution
Cation-donating agents: may reduce the potassium binding effectiveness of Calcium Resonium.

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 (sodium form).

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 and/or hypercalcaemia are allowed to develop (see section 4.4 Special warnings and 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 Calcium Resonium 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 hypokalaemia and hypercalcaemia, and their related clinical manifestations (see Section 4.4 Special warnings and precautions for use and Section 4.9 Overdose).

Cases of hypomagnesaemia have been reported.

Hypercalcaemia has been reported in well dialysed patients receiving calcium resin, and occasionally in patients with chronic renal failure. Many patients in chronic renal failure have low serum calcium and high serum phosphate, but some, who cannot be screened out beforehand, show a sudden rise in serum calcium to high levels after therapy with calcium resin. The risk emphasises the need for adequate biochemical control.

- **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.

The majority of cases have been reported with concomitant use of Sorbitol (see Section 4.4 Special warnings and precautions for use and Section 4.5 Interactions).

- **Respiratory, thoracic and mediastinal disorders**

Some cases of acute bronchitis and/or broncho-pneumonia associated with inhalation of particles of calcium 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

4.9 Overdose

Biochemical disturbances from overdosage may give rise to clinical signs or 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 or hypercalcaemia; cardiac arrhythmia 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: All other therapeutic products; Drugs for treatment of hyperkalemia and hyperphosphatemia
ATC code: V03AE01

Ion-exchange resin

5.2 Pharmacokinetic properties

Not applicable as this product is not absorbed.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber, which are additional to those already included in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Vanillin
Saccharin

6.2 Incompatibilities

Not applicable

6.3 Shelf life

5 years.

6.4 Special precautions for storage

Store in a dry place.

6.5 Nature and contents of container

HDPE bottle with a LDPE cap containing 300g Calcium Resonium, together with a plastic scoop, which, when filled level, contains approximately 15g.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Aventis Pharma Limited
One Onslow Street
Guildford
Surrey
GU1 4YS
UK

or trading as:

Sanofi-aventis or Sanofi
One Onslow Street
Guildford
Surrey
GU1 4YS
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 04425/0620

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24 April 1990
Date of latest renewal: 19 July 2003

10 DATE OF REVISION OF THE TEXT

15 January 2014

LEGAL CLASSIFICATION

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