1.6 PRODUCT INFORMATION

1.6.1 *Prescribing information (Summary of Product Characteristics)*

1. Name of the medicinal product

Less-K Powder

2. Qualitative and quantitative composition

Each sachet contains Calcium Polystyrene Sulfonate 5grams

For a full list of excipients, see section 6.1.

3. Pharmaceutical form

Powder for oral/rectal suspension

A cream to light brown, fine powder with orange flavor filled into a sachet

4. Clinical particulars

4.1 Therapeutic indications

Calcium Polystyrene Sulfonate is an ion-exchange resin that is recommended for the treatment of hyperkalaemia associated with anuria or severe oliguria

4.2 Posology and method of administration

Calcium Polystyrene Sulfonate is for oral and rectal administration

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. The resin given by mouth as a suspension in a small amount off water (3 to 4ml per gram of resin). Or it may be mixed with some sweetened vehicle (but not fruit juices which contain potassium)

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

Lower dose should be used; 1 mmol potassium per gram of resin

Initial dose: 1g per kg off body weight daily in 3-4 divided doses

Maintenance dose: 0.5g pe kg of body weight daily in 3-4 divided doses

Rectal

Resin may be given rectally using a dose off at least as great as that which would be given orally, diluted in the same ratio as described for adults

Neonates:

Should be given by oral route

Rectal; 0.5 to 1g per kg of body weight would be employed

4.3 Contra-indications

• 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 Polystyrene Sulfonate 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

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

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

To be used with caution

Cation-donating agents: may reduce the potassium binding effectiveness of Calcium Polystyrene Sulfonate.

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

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

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 emphasizes 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

• 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.

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

Calcium polystyrene Sulphonate, the calcium salt of sulfonated polymer, is a cation-exchange resin that exchanges ions of potassium ion and other cations in the gastrointestinal tract. It is used to enhance potassium excretion in treatment of hyperkalemia and may be preferred to the sodium resin in ptients who cannot tolerate an increase in sodium load

5.2 Pharmacokinetic properties
After administration of Calcium polystyrene Sulfonate via oral or rectal route, calcium ion of Calcium polystyrene Sulfonate exchange for the potassium ion in the intestinal tract, particularly around the colon and the drug is excreted as unchanged polystyrene Sulfonate resin into the faeces without digestion and absorption. In consequence, potassium in the intestinal tracts is excreted outside the body.

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
Orange flavor

Saccharin

6.2 Incompatibilities
Not applicable

6.3 Shelf life
2 years.

6.4 Special precautions for storage
Store below 30^0C in a dry place, away from direct sunlight

6.5 Nature and contents of container
5gram powder in aluminium sachets in duplex board unit box

6.6 Special precautions for disposal and other handling
No special requirements.

7. Marketing authorisation holder

Mega lifesciences Public Company Limited

8. Marketing authorisation number(s)

1A 431/56

9. Date of first authorisation/renewal of the authorisation

Date of first authorisation: 26th December 2013

10. Date of revision of the text

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