SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

1. NAME OF THE MEDICINAL PRODUCT
Kchek Oral Sachets 15g

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each sachet contains 15 g of calcium polystyrene sulphonate.

Excipient with known effect
Each tablet also contains 0.06 mg of aspartame (see section 4.4).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Oral powder.

Cream-coloured, fine powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
Calcium polystyrene sulphonate is an ion-exchange resin that is recommended for the treatment of hyperkalaemia.

4.2 Posology and method of administration

Posology
Calcium polystyrene sulphonate is for oral or rectal administration only. The dosage recommendations detailed below are a guide only; the precise requirements should be decided based on regular serum electrolyte determinations.

Adults, including the elderly
Oral
The usual dose is 15 g 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 4 ml 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 30 g resin in 150 ml 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 at least nine hours and 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.

Paediatric population
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 1 g/kg body weight daily in divided doses, in acute hyperkalaemia. Dosage may be reduced to 0.5 g/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 polystyrene sulphonate should not be given by the oral route. With rectal administration, the minimum effective dosage within the range of 0.5 g/kg to 1g/kg should be employed, diluted as for adults with adequate irrigation to ensure recovery of the resin.

4.3 Contraindications

- Hypersensitivity to the active substance or any of the excipients listed in section 6.1.
- In patients with plasma potassium levels below 5 mmol/litre.
- Conditions associated with hypercalcaemia (e.g., hyperparathyroidism, multiple myeloma, sarcoidosis or metastatic carcinoma).
- History of hypersensitivity to polystyrene sulphonate resins.
- Obstructive bowel disease.
- Calcium polystyrene sulphonate 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

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 sulphonate alone or in combination with sorbitol. Concomitant use of sorbitol with polystyrene sulphonate is not recommended (see section

4.5 and section 4.8).

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

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 sulphonate is not 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). 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 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.

In adults, symptomatic response to therapy with pantoprazole does not preclude the presence of gastric malignancy. Consider additional follow-up and diagnostic testing in adult patients who have a suboptimal response or an early symptomatic relapse after completing treatment with a PPI. In older patients, also consider an endoscopy.

Excipients
This medicine contains **aspartame**. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in

which phenylalanine builds up because the body cannot remove it properly. Neither non-clinical nor clinical data are available to assess aspartame use in infants below 12 weeks of age.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant use is not recommended
Sorbitol (oral or rectal): Concomitant use of Sorbitol with calcium polystyrene sulphonate is not recommended due to cases of intestinal necrosis and other serious gastrointestinal adverse reactions, which may be fatal (see section 4.4 and section 4.8).

To be used with caution
Cation-donating agents: may reduce the potassium binding effectiveness of calcium polystyrene sulphonate.

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).
Lithium: Possible decrease of lithium absorption. Levothyroxine: Possible decrease of levothyroxine absorption.

4.6 Fertility, pregnancy and lactation

Pregnancy
There is a limited amount of data on the use of calcium polystyrene sulphonate in pregnant women. Calcium polystyrene sulphonate is not recommended during pregnancy and in women of childbearing potential not using contraception.

Breastfeeding
There is insufficient information on the excretion of calcium polystyrene sulphonate in human milk. A risk to the newborns/infants cannot be excluded.

Fertility
There is no data available on fertility.

4.7 Effects on the ability to drive and use machines

Calcium polystyrene sulphonate has no or negligible influence on the ability to

drive and use machines.

4.8 Undesirable effects

The undesirable effects are classified as follows: Very common (□1/10) Common (□1/100 to <1/10) Uncommon (□1/1,000 to <1/100) Rare (□1/10,000 to <1/1,000) Very rare (<1/10,000)
Not known (cannot be estimated from the available data)

Table 1: Calcium polystyrene sulphonate undesirable effects

Metabolism and nutrition disorders	Common	Hypokalaemia, hypercalcaemia, hypomagnesaemia
	Uncommon	Decreased appetite
Respiratory, thoracic and mediastinal disorders	Very rare	Acute bronchitis and/or bronchopneumonia associated with inhalation of particles of calcium polystyrene sulphonate
Gastrointestinal disorders	Common	Nausea, vomiting, constipation
	Uncommon	Diarrhoea, gastric irritation, gastrointestinal ulcer, intestinal obstruction
	Rare	Faecaloma (faecal impaction) following rectal administration particularly in children and gastrointestinal concretions (bezoars) following oral administration. Gastrointestinal necrosis (colon necrosis), could lead to intestinal perforation which is sometimes fatal (see sections 4.4 and 4.5).

Reporting of suspected adverse reactions
Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org'

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

Pharmacological classification: 23.4 Ion exchange resins.

Calcium polystyrene sulphonate is an ion-exchange resin for the treatment of hyperkalaemia and hyperphosphatemia. It reduces serum levels of potassium and removes excess potassium from the body.

5.2 Pharmacokinetic properties

Not applicable as this product is not absorbed.

5.3 Drug interaction studies

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aspartame
Essence lemon dry

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and contents of the container

An airtight aluminium polyester foil sachet.

Fill weight: 15 g.
Pack size: 10 sachets per carton.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING ADRESS

La Renon Healthcare Pvt. Limited
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Gujar
at

India

Manufacturer:
Stanford Laboratories Private
Limited 8 Industrial Area
Mehatpur -
174315 Himachal
Pradesh India

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H2019/CTD5774/918ER/R1

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November 2023

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November 2023