

Package leaflet: Information for the user

Calcium Polystyrene Sulfonate 99.75% w/w powder for oral/rectal suspension

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Calcium Polystyrene Sulfonate is and what it is used for

Calcium Polystyrene Sulfonate 99.75% w/w powder for oral/rectal suspension contains a medicine called calcium polystyrene sulfonate (referred to as Calcium Polystyrene Sulfonate in this leaflet).

This belongs to a group of medicines called “ion exchange resins”.

This medicine is used to treat something called “hyperkalaemia”. This is when there is too much potassium in your blood. It works by attaching to potassium in your gut. This prevents potassium from entering your bloodstream and lowers potassium levels in your blood back to normal. It is often given to people who have kidney problems and people on dialysis.

2. What you need to know before you use Calcium Polystyrene Sulfonate

Do not use Calcium Polystyrene Sulfonate

- if you are allergic to calcium polystyrene sulfonate or any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- if you have been told that you have a low level of potassium in your blood
- if you have been told you have problems that result in high levels of calcium in your body such as thyroid problems or some types of cancer
- if your gut is partially or completely blocked (obstructive bowel disease)
- if you are taking a sweetener called sorbitol (a «sugar-free» sweetener used to sweeten food). This is because taking sorbitol and Calcium Polystyrene Sulfonate at the same time can cause narrowing of the gut wall (gastrointestinal stenosis) and reduced blood flow to the gut wall (intestinal ischemia) causing severe damage to your gut (necrosis and perforation). You must not take any sorbitol whilst using Calcium Polystyrene Sulfonate.

Do not use this medicine if any of the above applies to you. If you are not sure, talk to your doctor, pharmacist or nurse before using Calcium Polystyrene Sulfonate.

Warnings and precautions

Talk to your doctor or pharmacist before taking the Calcium Polystyrene Sulfonate:

- if it is for your baby, and they were premature, had a low birth-weight or have reduced gut movement,
- if you suffer from constipation.
- if you have abnormal bowel movements due to your medical condition (including conditions after surgery or drug usage) as these may cause a variety of disorders including bloating, severe constipation, reduced blood supply to your gut or ruptured bowel.

If you are not sure if any of the above apply to you, talk to your doctor, nurse or pharmacist before using Calcium Polystyrene Sulfonate.

Other medicines and Calcium Polystyrene Sulfonate

Tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines. This includes medicines you can buy without prescription, including herbal medicines. This is because Calcium Polystyrene Sulfonate can affect the way other medicines work. Also, some medicines can affect the way Calcium Polystyrene Sulfonate works.

In particular, check with your doctor if you are taking the following medicines:

- Medicines that contain salts such as magnesium, potassium or calcium. Ask your doctor if you are not sure
- Some medicines for constipation (laxatives) that contain magnesium
- Some medicines for indigestion (antacids) that contain magnesium or aluminium
- Digoxin or similar medicines from digitalis - for heart problems
- Levothyroxine or thyroxine - for an under-active thyroid
- Lithium - for mental illness

If you are not sure if any of the above applies to you, talk to your doctor, pharmacist or nurse before using Calcium Polystyrene Sulfonate.

Calcium Polystyrene Sulfonate with food and drink

Do not mix this medicine with fruit juice, this will stop this medicine from working properly.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

Driving and using machines

It is not known whether the administration of calcium polystyrene sulfonate may impair your ability to drive or use machines.

This medicine contains a maximum of 35 mg sodium benzoate per dose.

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially “sodium-free”. To be taken into consideration by patients on a controlled sodium diet.

3. How to use Calcium Polystyrene Sulfonate

Always use this medicine exactly as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure.

- The dose will depend on the results of blood tests
- For children the dose is also worked out according to how much the child weighs

Using this medicine

- Calcium Polystyrene Sulfonate can be given by mouth or put into the back passage (rectum).

- The suspension should be prepared immediately before use.
- If given by mouth, mix with a small amount of water and stir until it is thoroughly mixed. The powder does not dissolve but forms a suspension. You may add more water to the mixture to help you swallow the medicine. If powder remains in the glass after drinking, add more water, stir and drink immediately. You may need to do this again to make sure that you have taken all the powder.
- Calcium Polystyrene Sulfonate can also be made into a paste with something sweet, such as jam or honey.
- Do not mix the powder with fruit juice, this will stop the medicine from working properly.
- If given by mouth, it is important to sit up while taking the medicine so that you do not breathe in any powder into your lungs.
- If given by the back passage you should try to keep the medicine in your back passage for at least 9 hours. Then it needs to be thoroughly washed out.

The recommended dose:

Adults (including the elderly)

By mouth

- The usual dose is 15 g (one spoonful) three or four times a day

Into the back passage

- The usual dose is 30 g (two spoonfuls) once a day

In some cases, the medicine may be given both by mouth and into the back passage. This is where your potassium levels need to be lowered more quickly.

Use in children

If your child cannot take the medicine by mouth, it may be given into the back passage.

- The daily dose is 1 g for each kilogram of bodyweight
- Once the medicine has started working the dose may be lowered to 0.5 g daily for each kilogram of bodyweight

New-born babies

Calcium Polystyrene Sulfonate is only given into the back passage.

- The daily dose is between 0.5 g and 1 g for each kilogram of bodyweight.

It is important to give the right dose for children and babies. If too much is given, children and babies could get serious constipation.

If you use more Calcium Polystyrene Sulfonate than you should

It is unlikely that your doctor or nurse will give you too much medicine. Your doctor and nurse will be checking your progress and checking the medicine that you are given. Ask them if you are not sure why you are getting a dose of medicine.

If you are given too much Calcium Polystyrene Sulfonate the following effects may happen:

- Feeling irritable or confused
- Being unable to concentrate
- Muscle weakness and poor reflexes leading to paralysis
- Breathing problems
- Faster or pounding heartbeat
- Muscle cramps

If you forget to use Calcium Polystyrene Sulfonate

Your doctor or nurse will give instructions about when to have your medicine. It is unlikely that a dose will be missed. If you think that you may have missed a dose, talk to your doctor or nurse.

Do not use a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Talk to your doctor or nurse straight away if you notice any of the following serious side effects:

- Severe stomach pain, rectal pain
- Bloating, severe constipation
- Severe nausea and vomiting
- Black, bloody or tarry stools, coughing up blood or vomit that looks like coffee grounds.

Talk to your doctor or nurse if you get any of the following side effects:

Common (may affect up to 1 in 10 people)

- feeling tired, confused, having muscle weakness, cramps or a change in heart rate. These may be due to having low levels of potassium in your body
- high levels of calcium in your blood
- low levels of magnesium in your blood
- nausea
- vomiting
- constipation

Uncommon (may affect up to 1 in 100 people)

- loss of appetite
- diarrhoea
- stomach upset, pain in your gut or blockage of the gut
- gastrointestinal ulcer
- intestinal obstruction

Rare (may affect up to 1 in 1,000 people)

- large, hard, dry stool mass (faecalomas) in severe cases, particularly in children following rectal administration.
- a mass found trapped in the gastrointestinal system (bezoars) following oral administration.
- necrosis (death of the cells) of the colon, which could lead to intestinal perforation which is sometimes fatal, especially if it is administered together with sorbitol (a laxative).

Very rare (may affect up to 1 in 10,000 people)

- feeling short of breath or coughing. This could be the first sign of a serious chest infection. This can be caused by accidentally breathing in this medicine.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Calcium Polystyrene Sulfonate

Keep this medicine out of the sight and reach of children.

This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the bottle or carton label after “Exp”. The expiry date refers to the last day of that month.

Shelf life after first opening the 400 g or 300 g multi-dose container: 1 month.

Storage conditions after first opening of the 400 g or 300 g multidose container: Do not store above 25°C and keep the container tightly closed.

The single use 15 g sachets should be used immediately after opening.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Calcium Polystyrene Sulfonate contains

- The active substance is calcium polystyrene sulfonate. Each 100 g powder for suspension contain 99.75 g calcium polystyrene sulfonate.
- The other ingredients are: vanilla flavour (it contains sodium benzoate E 211).

What Calcium Polystyrene Sulfonate looks like and contents of the pack

Calcium Polystyrene Sulfonate is a golden or brown fine powder with slight vanilla flavour.

Calcium Polystyrene Sulfonate is supplied in:

- Plastic multi-dose container with 400 g or 300 g of powder fitted with a screw cap with a safety seal, and with a plastic measuring spoon, which, when filled level, contains 15 g of powder.
- Box of 26 sachets containing 15 g of powder.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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