

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



calcium polystyrene sulfonate

For oral or rectal administration after reconstitution.

Calcium Cycle Ion Exchange Resin

Flavoured powder form of calcium polystyrene sulfonate for removing excess potassium from the body.

One level measuring spoon contains 15g of Calcium Resonium.

300g powder

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Always read the leaflet attached before use and for details of dosage regime.

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Use as directed by your doctor.

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

STORE BELOW 25°C IN A DRY PLACE

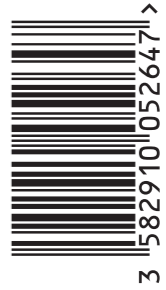
Marketing Authorisation Holder:

Sanofi

One Onslow Street,
Guildford, Surrey, GU1 4YS, UK

Manufacturer:

Sanofi Winthrop Industrie
196, rue du Maréchal Juin,
45200 Amilly - France



PACKAGE LEAFLET: INFORMATION FOR THE USER

Calcium Resonium® 99.934% w/w
Powder for Oral / Rectal Suspension
calcium polystyrene sulfonate



Read all of this leaflet carefully 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, nurse or pharmacist.
- This medicine is only for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

In this leaflet:

1. What Calcium Resonium is and what it is used for
2. Before you are given Calcium Resonium
3. How Calcium Resonium is given
4. Possible side effects
5. How to store Calcium Resonium
6. Further information

1. WHAT CALCIUM RESONIUM IS AND WHAT IT IS USED FOR

Calcium Resonium contains a medicine called calcium polystyrene sulfonate. This belongs to a group of medicines called 'ion exchange resins'. Calcium Resonium is used to treat something called 'hyperkalaemia'. This is when there is too much potassium in your blood. It works by removing this extra potassium

to bring your levels back to normal. It is often given to people who have kidney problems and people on dialysis.

2. BEFORE YOU ARE GIVEN CALCIUM RESONIUM

Do not use this medicine and tell your doctor or nurse if:

- You are allergic (hypersensitive) to calcium polystyrene sulfonate or any of the other ingredients in this medicine (listed in section 6 Further information). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- You have been told that you have a low level of potassium in your blood
- 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.
- Your gut is partially or completely blocked (obstructive bowel disease)
- You are taking a sweetener called sorbitol (a «sugar-free» sweetener used to sweeten food). This is because taking sorbitol and Calcium Resonium 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 Resonium.

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

Take special care and check with your doctor, nurse or pharmacist before using Calcium Resonium if:

- It is for your baby, and they were premature, had a low birth-weight or have reduced gut movement.

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

Taking other medicines

Please tell your doctor, nurse or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you can buy without prescription, including herbal medicines. This is because Calcium Resonium can affect the way other medicines work. Also some medicines can affect the way Calcium Resonium 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, nurse or pharmacist before using Calcium Resonium.

Pregnancy and breast-feeding

Talk to your doctor before using this medicine if:

- You are pregnant, might become pregnant, or think you may be pregnant.
- You are breast-feeding or planning to breast-feed.

Ask your doctor or pharmacist for advice before taking any medicine.

3. HOW CALCIUM RESONIUM IS GIVEN

Your doctor or nurse will normally give you this medicine. If you are not sure why you are being given Calcium Resonium or have any questions about how much Calcium Resonium is being given to you, speak to your doctor, nurse or pharmacist.

- 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.

Having the medicine

- Calcium Resonium can be given by mouth or put into the back passage (rectum).
- If given by mouth the powder can be swallowed with a little water or be made into a paste with something sweet, such as jam or honey.
- It should not be mixed with fruit juice, this will stop the medicine 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.

**How much is normally given:
Adults (including the elderly)**

By mouth

- The usual dose is 15g (one spoonful) three or four times a day.
- Take at least 3 hours before or 3 hours after other oral medicines you may be taking. If you suffer from gastroparesis (a condition where your stomach can't empty itself in the normal way), leave at least 6 hours before or after

taking other oral medicines.

Into the back passage

- The usual dose is 30g (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.

Children

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

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

New-born babies

Calcium Resonium is only given into the back passage

- The daily dose is between 0.5g and 1g 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 have more Calcium Resonium 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 Resonium 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 miss a dose of Calcium Resonium

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.

If you stop being given Calcium Resonium

Keep having Calcium Resonium until your doctor tells you to stop. If you stop having Calcium Resonium, your illness may come back.

Blood Tests

Your doctor may do regular blood tests while you are taking this medicine. This is to check the levels of salts (potassium, sodium, calcium and magnesium) in your blood.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Calcium Resonium can cause side effects, although not everybody gets them.

Tell a doctor or nurse straight away if you notice any of the following serious side effects:

- You have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- Blood in your sick (vomit) or black tarry stools.

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

- 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.
- Feeling jittery, having fits or muscle cramps. This may be due to low levels of calcium or magnesium in your body.
- Increased thirst or needing to go to the toilet more often.
- High blood pressure, kidney problems, heart problems or swelling in your limbs. This may be due to high levels of sodium in your body.
- Stomach upset, pain in your gut, narrowing or blockage of the gut.
- Reduced blood flow to the gut wall causing severe abdominal (tummy) pain, or collapse.
- Loss of appetite.
- Feeling sick, being sick, constipation or diarrhoea.
- 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.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE CALCIUM RESONIUM

This medicine will be kept by your doctor or pharmacist in a safe place where children cannot see or reach it.
Store below 25°C, in a dry place.

Do not use Calcium Resonium after the expiry date which is stated on the container. The expiry date refers to the last date of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Calcium Resonium contains

- 99.934% w/w of the active substance, calcium polystyrene sulfonate.
- The other ingredients are saccharin and vanillin.

What Calcium Resonium looks like and contents of the pack

Calcium Resonium is a cream or light brown coloured, fine powder. It is supplied in containers of 300g with a 15g scoop.

Marketing Authorisation Holder

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Manufacturer

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This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor, nurse or pharmacist.

This leaflet was last revised in November 2018.