



Calcium Resonium®



99.934%w/w Powder for Oral or Rectal Suspension
calcium polystyrene sulphonate

Powder for oral or rectal administration after reconstitution.

Calcium Cycle ion Exchange Resin.

The product also contains saccharin and vanillin.

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

KEEP THE CONTAINER TIGHTLY CLOSED IN ORDER TO PROTECT FROM MOISTURE.



300g powder



One measuring spoon contains 15g of Calcium Resonium.

Once diluted the product should be used immediately.

Discard any unused portion.

Please refer to leaflet attached before use and for details of dosage regimen.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

PA540/141/1

sanofi-aventis Ireland Ltd. T/A SANOFI

Citywest Business Campus

Dublin 24.



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GLUED PART

**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

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

calcium polystyrene sulphonate

Is this leaflet hard to see or read?

Phone 01 403 5600 for help



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 sulphonate. 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 sulphonate 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 (used to sweeten food). This is because taking sorbitol and Calcium Resonium at the same time can damage your gastrointestinal tract which may be fatal
- 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.

- Calcium Resonium has the potential to bind to other orally administered medications, which could affect how the medicine works. Dosing separation of Calcium Resonium from other orally administered medications is recommended. See section 3. How Calcium Resonium is given.

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 mouth Calcium Resonium should be given at least 3 hours before or after other oral medications. For patients with a disease of the muscles of the stomach (Gastroparesis) a 6 hour separation should be considered.
- 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

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.

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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 T in your

body (hypercalcemia/hypomagnesemia)

- Feeling jittery, having fits or muscle cramps. This may be due to low levels of calcium 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 or blockage of the gut
- Loss of appetite
- Feeling sick, being sick, constipation or diarrhoea
- Intestinal Necrosis
- 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

Talk to your doctor, nurse or pharmacist if any of the side effects gets serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafty@hpra.ie . By reporting side effects you can help provide more information on the safety of this medicine.

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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. Keep the container tightly closed in order to protect from moisture.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

Do not use Calcium Resonium after the expiry date which is stated on the label after EXP. 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 sulphonate
- The other ingredients are saccharin and vanillin

What Calcium Resonium looks like and contents of the pack

Calcium Resonium is a buff coloured powder. It is supplied in containers of 300g with a 15g scoop.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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email: IEmedinfo@sanofi-aventis.com

Manufacturer

Sanofi Winthrop Industrie, 196 avenue du Maréchal Juin, 45200 Amilly, France
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 January 2019.

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