Calcium Resonium[®]

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Calcium Resonium?

Calcium Resonium contains the active ingredient calcium polystyrene sulfonate. Calcium Resonium is used to help remove excessive amounts of potassium from the blood. For more information, see Section 1. Why am I using Calcium Resonium? in the full CMI.

2. What should I know before I use Calcium Resonium?

Do not use if you have ever had an allergic reaction to Calcium Resonium or any of the ingredients listed at the end of the CMI, have a bowel obstruction, have high calcium levels in the blood, have high levels of parathyroid hormone, have multiple myeloma (a cancer of the blood) or sarcoidosis, or have low levels of potassium. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section 2. What should I know before I use Calcium Resonium? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Calcium Resonium and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Calcium Resonium?

- Calcium Resonium can be given by mouth or rectally (via the back passage).
- The usual oral doses are 15 g three to four times daily for adults, and 1 g/kg of body weight in divided doses for children. Do not take Calcium Resonium with fruit juices or sorbitol. Take Calcium Resonium at least 3 hours before or 3 hours after other oral medications.
- The usual rectal doses are 30 g in 150 mL of water or 10% dextrose in water, as a retention enema for adults, with lower dosages usually used for infants and children. For newborn babies, the minimum effective dose range 0.5 g/kg to 1 g/kg should be used.

More instructions can be found in Section 4. How do I use Calcium Resonium? in the full CMI.

5. What should I know while using Calcium Resonium?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using Calcium Resonium. Be sure to keep all of your appointments with your doctor so that your progress can be checked. If you become pregnant while you are taking this medicine, stop taking it and tell your doctor or pharmacist immediately.
Things you should not do	 Do not take more than the recommended dose unless your doctor tells you to. Do not give this medicine to anyone else, even if they have the same condition as you. Do not use this medicine to treat any other complaints unless your doctor tells you to. Do not stop taking Calcium Resonium, or lower the dosage, without checking with your doctor.
Looking after your medicine	 Keep Calcium Resonium in a cool, dry place where the temperature stays below 30°C. Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it in the bathroom or near a sink, in the car, or on window sills. Keep it where young children cannot reach it.

For more information, see Section 5. What should I know while using Calcium Resonium? in the full CMI.

6. Are there any side effects?

Less serious side effects include nausea and vomiting, constipation, diarrhoea, muscle cramps, loss of appetite and gastric irritation. Speak to your doctor if you have any of these less serious side effects and they worry you. Serious side effects include swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing, hives, fainting, severe stomach pain, rectal pain, bloating, severe constipation, severe nausea and vomiting, black, blood or tarry stools, coughing up blood, or vomit that looks like coffee grounds. Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Calcium Resonium®

Active ingredient: calcium polystyrene sulfonate

Consumer Medicine Information (CMI)

This leaflet provides important information about using Calcium Resonium. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Calcium Resonium.

Where to find information in this leaflet:

- 1. Why am I using Calcium Resonium?
- 2. What should I know before I use Calcium Resonium?
- 3. What if I am taking other medicines?
- 4. How do I use Calcium Resonium?
- 5. What should I know while using Calcium Resonium?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Calcium Resonium?

Calcium Resonium contains the active ingredient calcium polystyrene sulfonate. Calcium polystyrene sulfonate contains calcium atoms. This calcium is swapped for potassium in the body, particularly in the large intestine. Calcium Resonium does not enter the bloodstream from the intestine. It is passed (with the potassium ions) with the faeces.

Calcium Resonium is used to help remove excessive amounts of potassium from the blood.

2. What should I know before I use Calcium Resonium?

Warnings

Do not use Calcium Resonium if:

- you are allergic to calcium polystyrene sulfonate or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you have a bowel obstruction
- you have high calcium levels in the blood
- you have high levels of parathyroid hormone (PTH)
- you have multiple myeloma (a cancer of the blood) or sarcoidosis (an inflammatory disorder)
- you have low levels of potassium (less than 5 mmol/L).

Check with your doctor if you:

- have any other medical conditions, especially the following:
 - o conditions thyroid conditions
 - constipation
 - o delayed gastric emptying
 - you have abnormal bowel movements (after surgery or drug usage), as these may cause a variety of disorders including colonic distension

- and severe constipation (bowel movements occur less often than usual or consist of hard, dry stools that are often painful or difficult to pass)
- o bone marrow (blood) disorders or tumours
- · take any medicines for any other condition
- plan to have surgery
- you are taking a sweetener called sorbitol (a sugarfree sweetener used to sweeten food). This is because taking Calcium Resonium alone or taking sorbitol 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. <u>Are there any side effects</u>?

Pregnancy and breastfeeding

Do not take it if you are pregnant or intend to become pregnant. Like most medicines of this kind, Calcium Resonium is not recommended to be used during pregnancy.

Do not take it if you are breastfeeding or intend to breastfeed. It is not known whether Calcium Resonium passes into breast milk.

Newborn babies

- Do not give oral Calcium Resonium to newborn babies. Orally administered Calcium Resonium has caused bowel obstruction in newborns.
- Calcium Resonium should only be given rectally to newborns.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Calcium Resonium and affect how it works.

These include:

- sorbitol
- digoxin, a medicine used for heart problems
- laxatives
- thyroxine, a medicine for hypothyroidism
- lithium, a medicine which can be used to treat bipolar disorder
- antacids containing aluminium or magnesium

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Calcium Resonium.

4. How do I use Calcium Resonium?

Calcium Resonium can be given by mouth or rectally (via the back passage).

How much to take / use

- The amount of Calcium Resonium you need to take will depend upon the amount of potassium in your blood.
- Your doctor will decide exactly how much Calcium Resonium you need to take.
- Follow the instructions provided and use Calcium Resonium until your doctor tells you to stop.

The usual doses are:

Oral

Adults:

- 15 g three to four times daily. The spoon provided in the jar contains 15 g of powder when filled level.
- Children:
- 1 g/kg of body weight in divided doses.

Calcium Resonium powder is usually given by mouth as a suspension in a small amount of water (3-4 mL per gram of powder), or it may be mixed with some sweetened liquid (but not fruit juices, which contain potassium). For children it is preferably given with a drink (not a fruit juice because of the high potassium content) or a little jam or honey.

Do not take Calcium Resonium with fruit juices or sorbitol.

Take Calcium Resonium at least 3 hours before or 3 hours after other oral medications.

If you have been diagnosed with delayed gastric emptying, ask your doctor for instructions on when to take Calcium Resonium.

Once the mixture has been prepared it should be used straight away. If it needs to be stored, it should be stored for no longer than 24 hours. Once reconstituted, Calcium Resonium is a cream to light brown coloured suspension in which small white particles may be visible.

Rectal (via the back passage)

- Adults
- 30 g in 150 mL of water or 10% dextrose in water, as a retention enema. Your pharmacist will make this up.
- Infants & children:
- Lower dosages are usually used.
- Newborn babies (Neonates):
- Calcium Resonium should not be given by mouth.
- With rectal administration the minimum effective dose range 0.5 g/kg to 1 g/kg should be used.

- This enema should be retained for at least nine hours.
 Afterwards the colon needs to be irrigated to remove the Calcium Resonium.
- The enema will usually be given by a doctor or nurse.

If you forget to use Calcium Resonium

Do not try to make up for missed doses by taking more than one dose at a time. This may increase the chance of getting an unwanted side effect.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you use too much Calcium Resonium

If you think that you have used too much Calcium Resonium you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 in Australia or 0800 764 766 in New Zealand), or
- contact your doctor, or
- go to the Accident and Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Large doses of Calcium Resonium may cause serious potassium ion deficiency. If you take too much you may feel irritable, confused, have muscle weakness, have diminished reflexes or paralysis.

5. What should I know while using Calcium Resonium?

Things you should do

Take Calcium Resonium exactly as prescribed.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Your doctor will regularly check the potassium, calcium and magnesium levels in your blood. The doctor may change the dose or stop the Calcium Resonium depending on what the results of these blood tests are.

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are taking Calcium Resonium.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking this medicine.

Call your doctor straight away if you:

 If you become pregnant while you are taking this medicine, stop taking it and tell your doctor or pharmacist immediately.

Remind any doctor, dentist or pharmacist you visit that you are using Calcium Resonium.

Things you should not do

- Do not take more than the recommended dose unless your doctor tells you to.
- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.
- Do not stop taking Calcium Resonium, or lower the dosage, without checking with your doctor.

Looking after your medicine

 Keep Calcium Resonium in a cool, dry place where the temperature stays below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal or gut-related: nausea and vomiting constipation diarrhoea muscle cramps loss of appetite gastric irritation	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Allergic reaction-related: • swelling of the face, lips, mouth	Call your doctor straight away, or go
or throat, which may cause difficulty in swallowing or breathing	straight to the Emergency

hives
 fainting
 Gastrointestinal or gut-related:
 severe stomach pain, rectal pain
 bloating, severe constipation
 severe nausea and vomiting
 Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

black, bloody or tarry stools,

looks like coffee grounds

coughing up blood or vomit that

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems in Australia or in New Zealand at https://pophealth.my.site.com/carmreportnz/s.

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

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Calcium Resonium contains

Active ingredient (main ingredient)	Calcium Resonium - each 100 g contains 99.934 g of Calcium Polystyrene Sulfonate
Other ingredients (inactive ingredients)	vanillin saccharin
Potential allergens	Calcium Resonium does not contain gluten, sucrose, lactose, tartrazine or any other azo dyes.

Do not take this medicine if you are allergic to any of these ingredients.

What Calcium Resonium looks like

Calcium Resonium is a buff-coloured powder with a vanilla odour (Aust R 12567).

Calcium Resonium comes in a container containing 300 g of powder. The container also contains a plastic spoon which, when filled level measures 15 g of powder.

Who distributes Calcium Resonium

Distributed in Australia by: sanofi-aventis australia pty ltd 12-24 Talavera Road

Macquarie Park NSW 2113

Freecall: 1800 818 806

Email: medinfo.australia@sanofi.com

Distributed in New Zealand by:

Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics

PO Box 62027

Sylvia Park Auckland 1644 Freecall: 0800 283 684

Email: medinfo.australia@sanofi.com

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