Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Calcium Resonium.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Calcium Resonium is used for

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

Calcium Resonium contains calcium polystyrene sulfonate which 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.

Your doctor, however, may prescribe Calcium Resonium for another purpose.

Ask your doctor if you have any questions about why it has been prescribed for you. This medicine is only available with a doctor's prescription.

Before you take it

When you must not take it Do not take Calcium Resonium if you have:

- a bowel obstruction
- · high calcium levels in the blood
- high levels of parathyroid hormone (PTH)
- multiple myeloma (a cancer of the blood) or sarcoidosis (an inflammatory disorder)
- low levels of potassium (less than 5 mmol/L).

Do not take Calcium Resonium if you are allergic to it or any of the ingredients listed at the end of this leaflet.

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

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.

Do not take it if you are pregnant or intend to become pregnant.

Do not take it if you are breastfeeding or planning to breastfeed.

Do not take it after the expiry date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is damaged or shows signs of tampering.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to:

- any of the ingredients listed at the end of this leaflet.
- any other medicines which contain polystyrene sulfonate resins,
- any other substances, such as foods, preservatives or dyes.

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant. Like most medicines of this kind, Calcium

Like most medicines of this kind, Calcium Resonium is not recommended to be used during pregnancy.

Tell your doctor or pharmacist if you are breastfeeding or planning to breastfeed.

It is not known whether Calcium Resonium passes into breast milk.

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- · thyroid conditions
- constipation
- · delayed gastric emptying
- bone marrow (blood) disorders or tumours

Tell your doctor if you plan to have surgery.

If you have not told your doctor or pharmacist about any of the above, tell them before you take Calcium Resonium.

Taking other medicines

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

Some medicines may interfere with Calcium Resonium. 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

These medicines may be affected by Calcium Resonium, or may affect how well it works. You may need to use different amounts of your medicine, or take different medicines. Your doctor or pharmacist will advise you.

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

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking Calcium Resonium.

How to take it

How it is given

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

How much to take

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. 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.

You will usually be given the enema by a doctor or nurse.

If you forget to take it

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 the next dose when you are meant to.

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

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

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764 766), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Calcium Resonium.

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.

While you are taking it

Things you must 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.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Calcium Resonium.

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.

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

Things you must 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

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.

Side effects

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor or pharmacist has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor as soon as possible if you do not feel well while you are taking Calcium Resonium.

It helps most people, but it may have unwanted side effects in a few people.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- nausea and vomiting
- · constipation
- diarrhoea
- · muscle cramps
- · loss of appetite
- · gastric irritation

These are mild side effects of this medicine and are usually short-lived.

If any of the following happen, stop taking this medicine and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- hives
- fainting

These are very serious side effects. If you have them, you may have had a serious allergic reaction to Calcium Resonium. You may need urgent medical attention or hospitalisation.

These side effects are very rare.

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

Other side effects not listed above may occur in some consumers.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

After taking it

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

Storage

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

Do not store it or any other medicine in the bathroom, near a sink, or on a windowsill.

Do not leave it in the car.

Heat and damp can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop taking Calcium Resonium, or the medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.

Return any unused medicine to your pharmacist.

Product description

What it looks like

Calcium Resonium is a buff coloured powder with a vanilla odour.

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.

Ingredients

Active Ingredient:

Calcium Resonium- Each 100 g contains 99.934 g of Calcium Polystyrene Sulfonate. Inactive Ingredients:

- vanillin
- saccharin.

Calcium Resonium does not contain gluten, sucrose, lactose, tartrazine or any other azo dyes.

Manufacturer/Sponsor

Calcium Resonium is made in France.

Calcium Resonium is supplied in Australia by:

sanofi-aventis australia pty ltd 12-24 Talavera Road Macquarie Park NSW 2113 Freecall No: 1800 818 806

Calcium Resonium is supplied in New Zealand by:

sanofi -aventis new zealand limited Level 8 56 Cawley Street Ellerslie Auckland

Freecall No: 0800 283 684

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