

IMPORTANT: PLEASE READ

CONSUMER INFORMATION RESONIUM CALCIUM®

(calcium polystyrene sulfonate powder)

This leaflet is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about RESONIUM CALCIUM. Contact your doctor, nurse or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

RESONIUM CALCIUM is used to remove high amounts of potassium from the blood.

What it does:

RESONIUM CALCIUM attaches to the extra potassium in the body, particularly in the large intestine, so it can be removed from the body in the stool.

When it should not be used:

Do not take RESONIUM CALCIUM if:

- You have a bowel obstruction (blocked intestine).
- You have medical conditions, such as thyroid problems or some types of cancer that result in high levels of calcium in your blood.
- You have low levels of potassium in your blood.
- You are allergic to calcium polystyrene sulfonate or any of the ingredients in the product (see **What the non-medicinal ingredients are**).

Do not give RESONIUM CALCIUM by mouth to newborn babies. RESONIUM CALCIUM should only be given rectally to newborns.

Do not use RESONIUM CALCIUM in newborn babies who have slowed movements in their gut (caused by other medications or following surgery).

What the medicinal ingredient is:

Calcium polystyrene sulfonate

What the non-medicinal ingredients are:

Saccharin, vanillin

What dosage forms it comes in:

Powder

WARNINGS AND PRECAUTIONS

BEFORE you use RESONIUM CALCIUM, talk to your doctor, nurse or pharmacist if you have or have had any medical conditions, especially the following:

- Problems with your bowel or constipation
- **Kidney problems**
- **Severe burns**
- **You are taking drugs that suppress your immune system**
- **You have heart problems and are taking the drug digitalis**
- Low blood volume, which can occur with dehydration or bleeding.
- **Electrolyte imbalance.** RESONIUM CALCIUM therapy can worsen these imbalances. Your doctor may want to check the levels of the electrolytes in your blood more frequently during treatment.
- **Breathing, lung or chest problems:** Accidental inhalation of the drug may cause acute bronchitis and/or pneumonia. Caution is advised not to inhale the medicine when ingesting it.
- You are pregnant or intend to become pregnant.
- You are breastfeeding. It is not known if RESONIUM CALCIUM passes into breast milk.

When taken by mouth, avoid taking RESONIUM CALCIUM at the same time as other orally administered medications (see "PROPER USE OF THIS MEDICATION").

Magnesium containing laxatives should not be used with RESONIUM CALCIUM.

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements or alternative medicines (non-prescription drugs or over the counter drugs).

When taken by mouth, RESONIUM CALCIUM may interfere with how other oral medicines are absorbed (see "PROPER USE OF THIS MEDICATION").

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The following may interact with RESONIUM CALCIUM:

- Digoxin, a medicine used for heart problems.
- Laxatives such as magnesium hydroxide or aluminium carbonate
- Thyroxine, a medicine for hypothyroidism
- Lithium, a medicine which can be used to treat bipolar disorder.
- Antacids containing aluminium or magnesium
- Sorbitol (a 'sugar free' sweetener used to sweeten food).

PROPER USE OF THIS MEDICATION

Usual dose:

RESONIUM CALCIUM can be given by mouth or in the rectum.

The amount of RESONIUM CALCIUM you need to take will depend upon the amount of potassium in your blood.

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

Your doctor will decide exactly how much RESONIUM CALCIUM you need to take. The usual doses are:

ORAL DOSING

When taken by mouth, RESONIUM CALCIUM should be taken at least 3 hours before or 3 hours after other oral medications. For patients with gastroparesis (a condition preventing your stomach from emptying properly), a 6-hour separation should be considered. Consult your health care provider for recommendations (see "WARNINGS AND PRECAUTIONS and INTERACTIONS WITH THIS MEDICATION").

RESONIUM CALCIUM powder is usually given by mouth mixed in a small amount of water. It can also be mixed with food or sweetened. Do NOT mix RESONIUM CALCIUM with orange juice or fruit juice which contains potassium.

RESONIUM CALCIUM is a powder. Be careful not to inhale it accidentally. Breathing in the powder may cause coughing and shortness of breath.

Adults, including the elderly:

15 g three to four times daily as indicated above. The spoon provided in the jar contains 15 g of powder when filled level.

Children:

You should follow the dosing recommended by your doctor.

For children, RESONIUM CALCIUM is preferably given with a drink (NOT a fruit juice because of the high potassium content) or a little jam or honey.

Newborn babies (neonates)

RESONIUM CALCIUM should not be given by mouth.

RECTAL DOSING

The enema is usually given by a doctor or nurse.

Adults:

The enema should be prepared by the pharmacist or the nurse. If possible, the enema should be retained in the rectum for at least nine hours. Afterwards, the colon needs to be washed out to remove RESONIUM CALCIUM.

Children and newborn babies (neonates):

The enema should be prepared by the pharmacist or the nurse. The enema should be retained in the rectum for as long as possible. Afterwards, the colon needs to be washed out to remove RESONIUM CALCIUM.

Overdose:

Taking too much RESONIUM CALCIUM may reduce your potassium in your blood below the normal level. If you take too much, you may feel irritable, confused, have muscle weakness, have diminished reflexes or paralysis.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

Do not take a double dose to make up for the dose you have missed. If it is almost time for the dose, skip the dose you missed and take the next dose when you are meant to.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- Nausea and vomiting
- Diarrhea
- Loss of appetite

If any of these affects you severely, tell your doctor, nurse or pharmacist.

SERIOUS SIDE EFFECTS, AND WHAT TO DO ABOUT THEM

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Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Abdominal pain (pain in your stomach and rectum)			x
Allergic reaction (rash; itching; swelling of the face, tongue and throat; severe dizziness and trouble breathing)			x
Constipation (bloating and swelling of the abdomen)			x
Stomach irritation and bleeding (vomit that looks like coffee grounds)			x
Rectal bleeding (black bloody or tarry stools)			x
High level of calcium (nausea, constipation, loss of appetite, confusion, memory loss)		x	
Low level of potassium (muscle cramps, feeling tired, confused, having muscle weakness or change in the heart rate)		x	
Low level of magnesium: abnormal eye movements, seizures, feeling tired, muscle spasms or cramps, muscle weakness, numbness		x	
Fecal Impaction (a hard lump of stools causing leaking liquid stool, stomach pain, feeling the need to push, nausea, vomiting, loss of appetite) following rectal administration particularly in children,			x
Bowel obstruction (cramping, severe stomach pain, vomiting, bloating, constipation, inability to pass gas)			x
Bowel perforation (severe stomach pain, chills, fever, nausea vomiting)			x

This is not a complete list of side effects. For any unexpected effects while taking RESONIUM CALCIUM, contact your doctor or pharmacist.

HOW TO STORE IT

Store at room temperature (15 to 30 °C).
Keep out of reach and sight of children.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to

Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: www.sanofi.ca or by contacting the sponsor, sanofi-aventis Canada Inc., at: 1-800-265-7927

This leaflet was prepared by sanofi-aventis Canada Inc.

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