

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

RESONIUM CALCIUM®

Calcium Polystyrene Sulfonate Powder for Solution

Read this carefully before you start taking **RESONIUM CALCIUM** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **RESONIUM CALCIUM**.

What is **RESONIUM CALCIUM** used for?

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

How does **RESONIUM CALCIUM** work?

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.

What are the ingredients in **RESONIUM CALCIUM**?

Medicinal ingredients: Calcium polystyrene sulfonate

Non-medicinal ingredients: Saccharin, vanillin

RESONIUM CALCIUM comes in the following dosage forms:

Powder for Solution

Do not use **RESONIUM CALCIUM** if:

- You have a bowel obstruction (blocked intestine).
- You have any of the following medical conditions:
 - Hyperparathyroidism (too much parathyroid hormone in the blood)
 - Multiple myeloma (a type of cancer)
 - Sarcoidosis (a rare disease caused by inflammation)
 - Metastatic carcinoma (cancer that spreads)
- 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 are the ingredients in **RESONIUM CALCIUM**?**).

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).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take **RESONIUM CALCIUM. Talk about any health conditions or problems you may have, including if you:**

- Have problems with your bowel movements such as delayed bowel movement or constipation.
- Are undergoing dialysis or have any kidney problems.
- Have severe burns.
- Are taking drugs that suppress your immune system.
- Have heart problems and are taking the drug digitalis.
- Have low blood volume, which can occur with dehydration or bleeding.
- Have been told you have an electrolyte imbalance.
- Have breathing, lung or chest problems.
- Are pregnant, think you are pregnant, or intend to become pregnant.
- Are breastfeeding. It is not known if RESONIUM CALCIUM passes into breast milk.
- Are taking a sweetener called sorbitol (a sugar-free sweetener used to sweeten food).
- Have problems with your bowel, bowel movements, or delayed bowel movements (constipation) caused by drugs or following a surgery.

Other warnings you should know about:

Other oral medications: If you take RESONIUM CALCIUM orally (by mouth), it may bind to other medications that you take by mouth. This may make your other medications less effective. Take RESONIUM CALCIUM at least 3 hours before, or 3 hours after you take other oral medications.

Electrolyte imbalance: RESONIUM CALCIUM can cause an imbalance in your blood's electrolyte levels. It can decrease your potassium levels too much, decrease your magnesium levels and/or increase your calcium levels. During treatment with RESONIUM CALCIUM, your healthcare professional will monitor your electrolyte levels.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with RESONIUM CALCIUM:

- Other oral medications; take RESONIUM CALCIUM at least 3 hours before or 3 hours after you take other oral medications.
- Digoxin, a medicine used for heart problems.
- Laxatives such as magnesium hydroxide or aluminium carbonate.
- Thyroxine, a medicine used for a condition called 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).
- Drugs that slow the stomach from emptying (such as anticholinergics or narcotics).

How to take RESONIUM CALCIUM:

- Take RESONIUM CALCIUM exactly as your healthcare professional has told you to.
- RESONIUM CALCIUM is taken by mouth or in the rectum.

If taking RESONIUM CALCIUM by mouth:

Mix RESONIUM CALCIUM in a small amount of water or with some sweetened food such as jam or honey, to make a paste. Do NOT mix with orange juice or other fruit juices because these contain

potassium. RESONIUM CALCIUM is a powder, be careful not to inhale it accidentally. Make sure you take RESONIUM CALCIUM at least 3 hours before, or 3 hours after you take any other oral medication.

If taking RESONIUM CALCIUM in the rectum:

An enema of RESONIUM CALCIUM is usually prepared and given by a healthcare professional. After the enema, the colon should be washed out to remove the RESONIUM CALCIUM.

Usual dose:

ORAL DOSING

Adults: the usual dose is 15 g, 3 to 4 times daily. The spoon provided in the jar holds 15 g of powder when filled level.

Children: A healthcare professional will decide the dose.

Newborn babies: Do NOT give RESONIUM CALCIUM by mouth to newborn babies.

RECTAL DOSING

Adults: The enema should be left in the rectum for at least 9 hours.

Children and newborn babies: The enema should be left in the rectum for as long as possible, the healthcare professional will decide.

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.

If you think you, or a person you are caring for, have taken too much RESONIUM CALCIUM, contact a healthcare professional, 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.

What are possible side effects from using RESONIUM CALCIUM?

These are not all the possible side effects you may have when taking RESONIUM CALCIUM. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- Nausea and vomiting
- Diarrhea
- Loss of appetite

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNKNOWN FREQUENCY			
Abdominal pain (pain in your stomach and rectum)			x
Allergic reaction: difficulty swallowing or breathing, wheezing, feeling sick to your stomach and throwing up, hives or rash, swelling of the face, lips, tongue or throat.			x
Bowel obstruction or gastrointestinal stenosis (the bowel or part of the gastrointestinal tract): cramping, severe stomach pain, vomiting, bloating, constipation, inability to pass stool or gas, loss of appetite, swelling of the abdomen.			x
Constipation: bloating and swelling of the abdomen.			x
Fecal impaction (blocked colon from a mass of stool) following rectal administration, particularly in children: abdominal pain, nausea and vomiting, liquid stool, urge to move bowels, loss of appetite, weight loss, malaise.			x
Gastrointestinal Ischemia / Ischemic Colitis (slow or no blood flow to the intestines): abdominal cramps, abdominal pain, bright red bowel movement, weight loss, diarrhea, nausea bloating.			x
Gastrointestinal necrosis or Bowel perforation: severe stomach pain, chills, fever, nausea vomiting, bleeding from your rectum, swelling of the stomach, constipation, diarrhea, fever fainting, low urine and confusion.			x
Hypercalcemia (high level of calcium in the blood): nausea, constipation, loss of appetite, confusion, memory loss.		x	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Hypokalemia (low level of potassium in the blood): muscle weakness, muscle spasms, cramping, constipation, feeling of skipped heart beats or palpitations, fatigue, tingling or numbness.		x	
Hypomagnesemia (low level of magnesium in the blood): abnormal eye movements, fatigue, muscle spasms or cramps, muscle weakness, numbness.		x	
Peritonitis (swelling of the lining of the belly or stomach): abdominal pain or tenderness, bloating, fever, nausea and vomiting, loss of appetite, diarrhea, thirst, low urine, cannot pass stool or gas, fatigue, confusion.			x
Rectal bleeding: black bloody or tarry stools.			x
Stomach irritation and bleeding: vomit that looks like coffee grounds.			x

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

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/adverse-reaction-reporting.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.

Storage:

Store at room temperature (15 to 30 °C).

Keep out of reach and sight of children.

If you want more information about RESONIUM CALCIUM:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website www.sanofi.ca, or by calling 1-800-265-7927.

This leaflet was prepared by sanofi-aventis Canada Inc.

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