

PRODUCT MONOGRAPH
INCLUDING PATIENT MEDICATION INFORMATION

RESONIUM CALCIUM®
Calcium Polystyrene Sulfonate
Powder for solution, oral/rectal
Cation-Exchange Resin

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RECENT MAJOR LABEL CHANGES

7 WARNINGS AND PRECAUTIONS	07/2022
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PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

RESONIUM CALCIUM (calcium polystyrene sulfonate) is indicated in patients with hyperkalemia associated with anuria or severe oliguria. It reduces serum levels of potassium and removes excess potassium from the body. RESONIUM CALCIUM is indicated in all states of hyperkalemia due to acute and chronic renal failure; examples include use following abortion, complicated labor, incompatible blood transfusion, crush injury, prostatectomy, severe burns, surgical shock, and in cases of severe glomerulonephritis and pyelonephritis.

RESONIUM CALCIUM can also be useful in patients requiring dialysis. Serum potassium levels in acute renal failure often reach dangerous heights before a rise in blood urea indicates the need for hemodialysis. RESONIUM CALCIUM can be used to reduce these potassium levels and thereby postpone the need for the use of the artificial kidney machine until other causes make it necessary.

Patients on regular hemodialysis therapy may develop shunt difficulties and under dialysis occurs, resulting in serious hyperkalemia. In these circumstances it is advisable to give RESONIUM CALCIUM to control hyperkalemia during the period of under dialysis. When patients on routine hemodialysis present a dietary management problem and tend towards hyperkalemia, RESONIUM CALCIUM can be used to control blood potassium levels. Similarly, patients on prolonged peritoneal dialysis may develop intermittent hyperkalemia after a few weeks, possibly due to dietary problems. These patients also can be satisfactorily controlled with RESONIUM CALCIUM.

1.1 Pediatrics

Pediatrics (<18 years of age): Health Canada has authorized pediatric use. Oral administration of RESONIUM CALCIUM is contraindicated in neonates (see 2 CONTRAINDICATIONS and 7 WARNINGS AND PRECAUTIONS).

1.2 Geriatrics

Geriatrics: Health Canada has authorized geriatric use.

2 CONTRAINDICATIONS

RESONIUM CALCIUM is contraindicated in patients with:

- Serum potassium < 5 mmol/L
- Conditions associated with hypercalcemia (e.g. hyperparathyroidism, multiple myeloma, sarcoidosis or metastatic carcinoma)
- A history of hypersensitivity to polystyrene sulfonate resins
- Obstructive bowel disease
- Oral administration of RESONIUM CALCIUM is contraindicated in neonates. Administration of RESONIUM CALCIUM in neonates with reduced gut motility (postoperatively or drug induced) is contraindicated.

4 DOSAGE AND ADMINISTRATION

4.1 Dosing Considerations

Treatment with RESONIUM CALCIUM should be given as soon as the serum potassium level rises above 6 mmol/L (23.5 mg per 100 mL). The action may be delayed for one or two days since maximal exchange probably takes place in the colon. Exchange will continue until all the resin has been voided (this may be one or two days after administration has been discontinued). For this reason, RESONIUM CALCIUM therapy should be stopped when the serum potassium level has fallen to 5 mmol/L, otherwise, the continued action may lead to potassium depletion.

RESONIUM CALCIUM is for oral or rectal administration only. The following doses are suggested only as a general guide. The precise daily dose should be decided on the basis of regular clinical and serum electrolyte determination.

The amount of potassium taken up by RESONIUM CALCIUM will be largely determined by the length of time it is exposed to the high potassium concentration in the fecal water in the colon. For this reason, a tendency towards constipation should be encouraged and purgative drugs should be avoided.

4.2 Recommended Dose and Dosage Adjustment

Adults, Including the Elderly:

Oral

For adults the usual dose is 15 g, 3 or 4 times a day.

Rectal

In cases where vomiting may make oral administration difficult or in patients who have upper gastrointestinal tract problems, including paralytic ileus, RESONIUM CALCIUM may be given rectally as a suspension of 30 g RESONIUM CALCIUM in 100 mL of 2% methylcellulose and 100 mL of water, as a daily retention enema. In the initial stages, administration by this route as well as orally may help to achieve a more rapid lowering of the serum potassium level.

Since the rectal route is less effective than the oral route, the longer RESONIUM CALCIUM is retained the greater is the amount of potassium removed.

Children:

Oral

In smaller children and infants correspondingly smaller doses should be employed by using as a guide a rate of 1mEq of potassium per gram of RESONIUM CALCIUM as the basis for calculation. Children should be given 1 g/kg body weight of RESONIUM CALCIUM daily in divided doses, in acute hyperkalemia. In maintenance therapy the dose may be reduced to 0.5 g/kg body weight daily in divided doses.

Rectal

When RESONIUM CALCIUM is refused by mouth it may be given rectally suspended in a proportional amount of 10% dextrose in water, using a dose at least as great as that which would have been given orally.

Neonates

Oral administration of RESONIUM CALCIUM is contraindicated in neonates. (see 2 CONTRAINDICATIONS).

With rectal administration, the minimum effective dosage within the range of 0.5 g/kg to 1 g/kg should be employed, diluted as for adults and with adequate irrigation to ensure recovery of the resin (see 7 WARNINGS AND PRECAUTIONS).

4.3 Reconstitution

Oral

Adults, Including the Elderly and Children

RESONIUM CALCIUM may be made into a paste with some sweetened vehicle, but not orange juice or other fruit juices that are known to contain potassium. The amount of fluid usually ranges from 3 to 4 mL per gram of RESONIUM CALCIUM.

Rectal

Adults, Including the Elderly

RESONIUM CALCIUM may be given as a suspension of 30 g RESONIUM CALCIUM in 100 mL of 2% methylcellulose and 100 mL of water, as a daily retention enema.

Children

It may be given rectally suspended in a proportional amount of 10% dextrose in water, using a dose at least as great as that which would have been given orally.

Neonates

With rectal administration, the minimum effective dosage within the range of 0.5 g/kg to 1 g/kg should be employed, diluted as for adults and with adequate irrigation to ensure recovery of the resin.

4.4 Administration

Adults, Including the Elderly

Oral

RESONIUM CALCIUM is given by mouth as a suspension in a little water, or for greater palatability, the resin may be made into a paste. If there is difficulty with swallowing, it may be given through a gastric tube, 2 to 3 mm in diameter.

Administer RESONIUM CALCIUM at least 3 hours before or 3 hours after other oral medications. For patients with gastroparesis, a 6-hour separation should be considered (see 7 WARNINGS AND PRECAUTIONS).

Rectal

RESONIUM CALCIUM may be given as a daily retention enema. Since the rectal route is less effective than the oral route, the longer RESONIUM CALCIUM is retained the greater is the amount of potassium removed. The enema should, if possible, be retained for at least nine hours and then the colon irrigated to remove the resin.

If both routes are used initially, it is probably unnecessary to continue rectal administration once the oral resin has reached the rectum.

Children

Oral

RESONIUM CALCIUM should be given orally, preferably with a drink or a little jam or honey. It should not be given in fruit drinks and some carbonated beverages, since these have high potassium content.

Rectal

It may be given rectally suspended in a proportional amount of dextrose in water. Following retention of the enema, the colon should be irrigated to ensure adequate removal of the resin (see 7 WARNINGS AND PRECAUTIONS).

Neonates

Only rectal administration should be considered. Administration of RESONIUM CALCIUM in neonates with reduced gut motility (postoperatively or drug-induced) is contraindicated (see 2 CONTRAINDICATIONS).

5 OVERDOSAGE

Biochemical disturbances resulting from overdosage may give rise to clinical signs and symptoms of hypokalemia, including irritability, confusion, delayed thought processes, muscle weakness, hyporeflexia, and eventually frank paralysis. Apnea may be a serious consequence of this progression. Electrocardiographic changes may be consistent with hypokalemia or hypercalcemia; cardiac arrhythmia may occur. Appropriate measures should be taken to correct serum electrolytes (potassium, calcium). RESONIUM CALCIUM should be removed from the alimentary tract by appropriate use of laxatives or enemas.

For management of a suspected drug overdose, contact your regional poison control centre.

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

Table 1 – Dosage Forms, Strengths, Composition and Packaging

Route of Administration	Dosage Form / Strength/Composition	Non-medicinal Ingredients
oral/rectal	Powder for solution,	Saccharin, vanillin

RESONIUM CALCIUM is supplied in a white opaque HDPE jar containing 300 g. A plastic measure is included which holds 15 g of resin.

7 WARNINGS AND PRECAUTIONS

General

In neonates, RESONIUM CALCIUM should not be given by the oral route (see 2 CONTRAINDICATIONS).

Binding to other orally administered medications: When administered orally RESONIUM CALCIUM may bind to other orally administered medications, which could decrease their gastrointestinal absorption and efficacy. Avoid co-administration of RESONIUM CALCIUM with other orally administered medications. Administer RESONIUM CALCIUM at least 3 hours before or 3 hours after administration of other oral medications. For patients with gastroparesis, a 6-hour separation should be considered (see 9 DRUG INTERACTIONS and 4 DOSAGE AND ADMINISTRATION, Adults, including the Elderly).

Other risks

In the event of clinically significant constipation, treatment with the resin should be discontinued until normal bowel motions are resumed. Magnesium-containing laxatives should not be used (see 9 DRUG INTERACTIONS).

The patient should be positioned carefully when ingesting the resin, to avoid aspiration, which may lead to bronchopulmonary complications.

Due to the risk of severe gastrointestinal disorders the use of Polystyrene sulfonate is not recommended in patients with compromised gastrointestinal motility (including immediate post-surgery or drugs that decrease gastrointestinal motility, such as anticholinergics or narcotic analgesics).

Gastrointestinal

Gastrointestinal injuries: Cases of gastrointestinal stenosis, intestinal ischemia, ischemic colitis, peritonitis, gastro-intestinal tract ulceration, rectal haemorrhage, gastrointestinal necrosis and intestinal perforation with fatal outcomes have been reported in patients treated with RESONIUM CALCIUM alone or in combination with sorbitol. Although all patients are potentially susceptible, risk factors for gastrointestinal adverse events were present in many of the cases including prematurity, history of intestinal disease or surgery, hypovolemia, immunosuppressant therapy, severe burns, and renal insufficiency and failure. Patients should be advised to seek prompt medical attention in case of newly developed severe abdominal pain, nausea and vomiting, stomach distension and rectal bleeding. Concomitant administration of sorbitol with RESONIUM CALCIUM is not recommended (see 9 DRUG INTERACTIONS and 8 ADVERSE REACTIONS).

Monitoring and Laboratory Tests

Monitoring serum potassium and calcium levels should be undertaken at regular intervals.

Serum potassium monitoring and hypokalemia

During treatment with RESONIUM CALCIUM the possibility of severe potassium depletion should be considered. Adequate clinical control, as well as biochemical control by daily estimation of serum electrolytes and blood urea levels, is essential during treatment especially in patients on digitalis. To prevent serious hypokalemia, administration of RESONIUM CALCIUM should be discontinued as soon as the serum potassium level falls to 5 mmol/L (see 9 DRUG INTERACTIONS).

Hypomagnesemia, hypercalcemia, and other electrolyte disturbances

Like all cation-exchange resins, RESONIUM CALCIUM is not totally selective for potassium. Hypomagnesemia and/or hypercalcemia may occur. Accordingly, patients should be monitored for all applicable electrolyte disturbances.

Hypercalcemia has been reported in well dialysed patients receiving calcium resin, and occasionally in patients with chronic renal failure. Many patients in chronic renal failure have low serum calcium and high serum phosphate, but some, who cannot be screened out beforehand, show a sudden rise in serum calcium to high levels after therapy with calcium resin. The risk emphasizes the need for adequate biochemical control. Serum calcium levels should be estimated at weekly intervals to detect the early development of hypercalcemia. The dose of administered RESONIUM CALCIUM should be reduced to levels at which hypercalcemia is prevented.

7.1 Special Populations

7.1.1 Pregnant Women

RESONIUM CALCIUM is not absorbed from the gastrointestinal tract. No data are available about the use of polystyrene sulfonate resins in human pregnancy.

7.1.2 Breast-Feeding

RESONIUM CALCIUM is not absorbed from the gastrointestinal tract. No data are available about the use of polystyrene sulfonate resins in human lactation.

7.1.3 Pediatrics

In neonates, RESONIUM CALCIUM should not be given by the oral route (see 2 CONTRAINDICATIONS).

In both children and neonates, particular care should be observed with rectal administration, as excessive dosage or inadequate dilution could result in impaction of the resin.

Due to the risk of gastrointestinal tract hemorrhage or colonic necrosis, particular care should be observed in premature infants or low birth weight infants.

8 ADVERSE REACTIONS

8.5 Post-Market Adverse Reactions

Gastrointestinal disorders:

Intestinal intolerance due to the gritty consistency and bulk of the resin may be manifested by the appearance of general adverse effects including nausea, vomiting, gastric irritation, anorexia, constipation and occasionally, diarrhea. These adverse effects may be relieved by intermittent therapy and the use of mild laxatives where constipation is a factor.

Fecal impaction, following rectal administration, particularly in children, and gastrointestinal concretions (bezoars) following oral administration, have been reported. Gastrointestinal stenosis and intestinal obstruction have also been reported. This could possibly due to co-existing pathology or inadequate dilution of the resin.

Gastrointestinal ischemia, ischemic colitis, peritonitis, gastrointestinal stenosis, rectal haemorrhage, gastrointestinal tract ulceration or necrosis which could lead to intestinal perforation have been reported which is sometimes fatal.

Metabolism and nutrition disorders:

In accordance with its pharmacological actions, RESONIUM CALCIUM may give rise to hypokalemia and hypercalcemia and their related clinical manifestations (see 7 WARNINGS AND PRECAUTIONS and 5 OVERDOSAGE). Cases of hypomagnesemia have been reported.

Hypercalcemia has been reported in well dialysed patients receiving calcium resin, and occasionally in patients with chronic renal failure (see 7 WARNINGS AND PRECAUTIONS).

Respiratory, thoracic and mediastinal disorders:

Some cases of acute bronchitis and/or bronchopneumonia associated with inhalation of particles of calcium polystyrene sulfonate have been described.

9 DRUG INTERACTIONS

9.3 Drug-behavioural Interactions

Interactions with behaviour have not been established.

9.4 Drug-Drug Interactions

The drugs listed below are based on either drug interaction case reports or studies, or potential interactions due to the expected magnitude and seriousness of the interaction (i.e., those identified as contraindicated).

Aluminum hydroxide: Intestinal obstruction due to concretions of aluminum hydroxide has been reported when aluminum hydroxide was combined with the resin (sodium form).

Cation donating agents: These may reduce effectiveness of the resin in binding potassium.

Digitalic drugs: The toxic effects of digitalis on the heart, especially various ventricular arrhythmias and atrioventricular (A-V) nodal dissociation, are likely to be exaggerated if hypokalemia and/or hypercalcemia develop, even in the face of serum digoxin concentrations in the 'normal range' (see 7 WARNINGS AND PRECAUTIONS).

Lithium: Possible decrease of lithium absorption.

Non-absorbable cation-donating antacids and laxatives: Systemic alkalosis has been reported after cation-exchange resins were administered orally in combination with non-absorbable cation-donating antacids and laxatives such as magnesium hydroxide and aluminum carbonate.

Orally administered medications: When administered orally RESONIUM CALCIUM has the potential to bind to other orally administered medications. Binding of RESONIUM CALCIUM to other oral medications could cause decrease in their gastrointestinal absorption and efficacy. Dosing separation of RESONIUM CALCIUM from other orally administered medications is recommended (see 4 DOSAGE AND ADMINISTRATION and 7 WARNINGS AND PRECAUTIONS).

Sorbitol (oral or rectal): Concomitant administration of sorbitol with RESONIUM CALCIUM is not recommended due to cases of intestinal necrosis, perforation and other serious gastrointestinal adverse reactions, which may be fatal (see 7 WARNINGS AND PRECAUTIONS and 8 ADVERSE REACTIONS).

Thyroxine: Possible decrease of thyroxine absorption.

9.5 Drug-Food Interactions

Interactions with food have not been established.

9.6 Drug-Herb Interactions

Interactions with herbal products have not been established.

9.7 Drug-Laboratory Test Interactions

Interactions with laboratory tests have not been established.

10 CLINICAL PHARMACOLOGY

10.1 Mechanism of Action

RESONIUM CALCIUM (calcium polystyrene sulfonate) is a cation exchange resin prepared in the calcium phase. Each gram of resin has a theoretical *in vitro* exchange capacity of about 1.3 to 2 millimoles (mmol) of potassium (K^+). *In vivo*, the actual amount of potassium bound will be less than this. The sodium (Na^+) content of the resin is less than 1 mg/g. The calcium content is 1.6 to 2.4 mmol/g. The resin is insoluble in water. Calcium polystyrene sulfonate is not absorbed from the gastrointestinal tract.

RESONIUM CALCIUM acts by a cumulative process throughout the gastrointestinal tract, removing potassium ions which are excreted in the feces.

As the resin passes through the colon, it comes into contact with fluids containing increasing amounts of potassium. In the cecum the concentration of Na^+ and K^+ are similar to those in the small intestine. In the stool water of the sigmoid colon there may be 6-38 mmol/L sodium and 14-44 mmol/L potassium. The result is that potassium is taken up in increasing amounts in exchange for calcium ions. The length of time the resin remains in the body is a decisive factor in its effectiveness. For this reason oral administration is more effective than the use of enemas which should, if possible, be retained for 9

hours. The efficiency of potassium exchange is unpredictably variable. The resin is not selective for potassium.

10.3 Pharmacokinetics

Absorption

RESONIUM CALCIUM is not absorbed from the gastrointestinal tract.

Special Populations and Conditions

- **Pregnancy and Breast-feeding**

No data are available about the use of polystyrene sulfonate resins in human pregnancy and human lactation

11 STORAGE, STABILITY AND DISPOSAL

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

12 SPECIAL HANDLING INSTRUCTIONS

None.

PART II: SCIENTIFIC INFORMATION

13 PHARMACEUTICAL INFORMATION

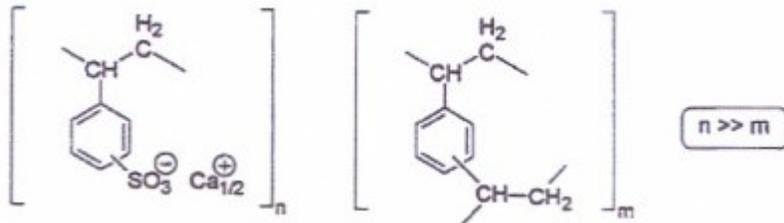
Drug Substance

Proper name: Resonium calcium

Chemical name: calcium polystyrene sulfonate

Molecular formula and molecular mass: $[C_8H_7SO_3Ca_{1/2}]_n [C_{10}H_{10}]_m$ and $10^{17} - 10^{19}$ dalton

Structural formula:



Product Characteristics:

RESONIUM CALCIUM (calcium polystyrene sulfonate), is a solid substance, cream to light brown fine powder with vanilla odor.

RESONIUM CALCIUM bears the chemical name of cross-linked polystyrene calcium sulfonate.

RESONIUM CALCIUM is a sulfonic acid resin in the calcium phase containing about 8% calcium. Its average binding capacity is 1.6 mmol of potassium per gram of resin. This implies a binding of 96 mmol of potassium by a daily dose of 60 g RESONIUM CALCIUM. The sodium content of the anhydrous resin is not more than 1 mg per gram.

14 CLINICAL TRIALS

No data available.

15 MICROBIOLOGY

No microbiological information is required for this drug product.

16 NON-CLINICAL TOXICOLOGY

General Toxicology: Segal et al demonstrated that amberlite IR-4 (a general range of cation exchange resins), could be fed to rats for eight months without any adverse effects on their growth and well-being, except that on the 20% dietary resin regime the growth of male rats was slightly inhibited.

McChesney and McAuliff carried out a similar study with sulfonic acid resins at a 10% dietary level and found the growth of male rats, but not of females, was slightly inhibited. The male rats however, thrived on sodium resins which led McChesney and McAuliff to conclude that the inhibition was related to acidosis or sodium deprivation.

Symptoms indicative of sodium depletion (excessive weight loss and weakness) or of potassium depletion (muscle weakness, mental confusion and apathy) may occur without adequate biochemical control. No studies have been published carried out in healthy volunteers.

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.

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