

PART III: CONSUMER INFORMATION**PrRENAGEL®****Sevelamer hydrochloride tablets**

This leaflet is part III of a three-part “Product Monograph” published when RENAGEL was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about RENAGEL. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

- the control of high phosphorus levels in patients with end-stage renal disease undergoing dialysis (whether hemodialysis or peritoneal dialysis).

What it does:

RENAGEL is a phosphate binder that is not absorbed in your body. When taken with meals RENAGEL inhibits intestinal absorption of ingested phosphate from food.

When it should not be used:

- in patients with low blood phosphorus levels
- in patients with bowel obstruction/blockage, or with known active damage to the lining of the digestive tract such as necrosis (death of tissue), perforation (hole), ulcers (sores) or bleeding.
- in patients allergic to sevelamer hydrochloride or one of the other ingredients in the product (See What the nonmedicinal ingredients are).

What the medicinal ingredient is:

Sevelamer hydrochloride

What the nonmedicinal ingredients are:

colloidal silicon dioxide; diacetylated monoglyceride; hypromellose; iron oxide black; isopropyl alcohol; propylene glycol; and stearic acid.

What dosage forms it comes in:

800 mg tablets

WARNINGS AND PRECAUTIONS**SERIOUS WARNING AND PRECAUTION**

RENAGEL may cause serious side effects that may require hospitalization and surgery. Tell your doctor or go to the hospital right away if you have difficulty swallowing, bowel obstruction, or bowel perforation.

RENAGEL tablets should be swallowed whole and should not be crushed, chewed, dissolved or broken into pieces.

BEFORE you use RENAGEL talk to your doctor or pharmacist if you:

- have difficulty swallowing (swallowing disorders or problems with your esophagus)
- have an intestinal disorder such as, conditions that slow down the passage of food through the intestine and lead to blockage.
- have had surgery on your intestines.
- have severe or worsening constipation
- have low phosphorus levels in your blood.
- have low calcium levels in your blood.
- are pregnant, plan to become pregnant or are nursing
- have any allergies to this drug or its ingredients or components of the container

INTERACTIONS WITH THIS MEDICATION

RENAGEL may affect the way other medicines work. Please tell your doctor or pharmacist what medicine you have recently taken, are taking or intend to take including those available without prescription and herbal remedies. These medicines may need to be taken one hour before or three hours after RENAGEL. Remember, RENAGEL must always be taken with food.

If you see another doctor or a dentist while you are using RENAGEL, you should tell them that you are using RENAGEL

Drugs that may interact with RENAGEL include: ciprofloxacin and levothyroxine. Your doctor may order blood tests to more closely monitor the thyroid hormones in your blood if you are taking levothyroxine and RENAGEL.

RENAGEL may also interact with drugs that are used to prevent the rejection of a transplanted organ, such as cyclosporin, mycophenolate and tacrolimus.

RENAGEL may interact with drugs that are used to treat stomach ulcer known as proton pump inhibitors (e.g. pantoprazole, omeprazole).

PROPER USE OF THIS MEDICATION

RENAGEL tablets should be swallowed whole and should not be crushed, chewed, dissolved or broken into pieces.

Usual starting dose:

Dosage is individualized. Your doctor will determine your dosage.

RENAGEL should be taken immediately prior to or with meals.

The total daily dose should be divided according to meal portions during the day.

Average Maintenance Dose: Approximately nine 800 mg tablets per day (equivalent to three 800 mg tablets per meal). Always follow your physician's dosage instructions.

Overdose:

In case of an overdose, contact your doctor or poison control center immediately

Missed Dose:

If a dose is forgotten, it should be skipped. Double dosing is not advisable.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Although RENAGEL is generally well tolerated, some patients may experience side effects, including: nausea, vomiting, diarrhea, indigestion, constipation, rash and itch.

Contact your doctor if you experience severe abdominal pain, stomach or intestine problems, or blood in the stool. These symptoms can be due to serious inflammatory bowel disease caused by crystal deposits in your bowel. Your doctor will decide whether or not you should continue treatment with RENAGEL.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	Abdominal pain		✓	
Uncommon	Dysphagia: Difficulty swallowing problems with your esophagus.	✓		

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
	Bowel Obstruction (ileus), Intestinal Blockage, or hole in the intestine,: sudden abdominal pain, inflammation and ulcers, abdominal discomfort, cramping and gas pains, diarrhea or difficulty passing stools, bleeding (blood in stools), nausea/vomiting especially after meals, excessive burping, loss of appetite; later symptoms include fever and chills			✓
Unknown	Diverticulitis: left lower quadrant pain, fever, nausea, diarrhea, or constipation		✓	
	Allergic reactions: rash, swelling of the face or mouth, difficulty breathing.			✓
	Inflammation of the bowel: Severe abdominal pain, stomach or intestine problems, blood in the stool.		✓	

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

HOW TO STORE IT

Store at controlled room temperature 15°C to 30°C. Protect from moisture.

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/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.

MORE INFORMATION

Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>); 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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