

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **RENAGEL**®

#### Sevelamer Hydrochloride Tablets

Read this carefully before you start taking **RENAGEL** 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 **RENAGEL**.

#### Serious Warnings and Precautions

RENAGEL may cause serious side effects that may require hospitalization and surgery. This can include:

- dysphagia (difficulty swallow that can cause food or liquid to get into the lungs);
- bowel obstruction (blockage that stops or impairs food or liquid from passing through the intestines); or
- bowel perforation (a hole in the wall of the intestines).

Tell your healthcare professional or go to the hospital right away if you have difficulty swallowing, nausea, vomiting, chills, fever, abdominal pain, constipation, or diarrhea. See the **Serious side effects and what to do about them** table below for more information on these and other serious side effects.

#### What is RENAGEL used for?

RENAGEL is used to control high phosphorus levels in adults with end-stage renal disease (ESRD) who are undergoing dialysis.

#### How does RENAGEL work?

RENAGEL belongs to a class of medicines known as phosphate binders. It works by binding to ingested phosphate from food in your stomach. This prevents phosphate from being absorbed into your body.

#### What are the ingredients in RENAGEL?

Medicinal ingredient: Sevelamer hydrochloride.

Non-medicinal ingredients: Colloidal silicon dioxide; diacetylated monoglyceride; hypromellose; and stearic acid.

#### RENAGEL comes in the following dosage forms:

Tablets: 800 mg of sevelamer hydrochloride.

#### Do not use RENAGEL if:

- you have low blood phosphorus levels in your blood.
- you have a bowel obstruction (blockage that stops or impairs food or liquid from passing through the intestines).
- you have active damage to the lining of the digestive tract such as necrosis (death of tissue), perforation (hole), ulcers (sores), or bleeding.
- you are allergic to sevelamer hydrochloride or any of the other ingredients in RENAGEL.

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

- have difficulty swallowing occurring in the mouth and/or the throat.
- have gastrointestinal problems (conditions that slow down the passage of food through the intestine and lead to blockage).
- have had any surgery on your intestines.
- have severe or worsening constipation.
- have low calcium levels in your blood.
- are pregnant or plan to become pregnant.
- are breast-feeding or plan to breast-feed.
- have kidney problems.

**Other warnings you should know about:**

- Your healthcare professional may conduct various tests depending on your health and if you take other medication. This may include tests to assess the levels of certain minerals, vitamins, and hormones in your blood. They will interpret these results and may adjust or stop your dose or provide the necessary supplements.

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

**The following may interact with RENAGEL:**

- ciprofloxacin, a medicine used to treat certain bacterial infections.
- cyclosporin, mycophenolate mofetil, and tacrolimus, medicines used to prevent the rejection of a transplanted organ. These medicines should be taken at least one hour before or three hours after taking RENAGEL.
- levothyroxine, a medicine used to treat hypothyroidism (a condition where the thyroid gland does not produce enough thyroid hormone).
- proton pump inhibitors, medicines used to treat stomach ulcers (e.g., pantoprazole and omeprazole).
- antiarrhythmic, medicines used to treat or prevent irregular heartbeats.
- anticonvulsants, medicines used to treat seizures.

**How to take RENAGEL:**

- Take RENAGEL exactly as directed by your healthcare professional.
- RENAGEL tablets is for oral use and should be swallowed whole. Do NOT crush, chew, bite, or break the tablets before swallowing.
- Take RENAGEL immediately before or with meals.

**Usual dose:**

Your healthcare professional will decide the right dose and length of RENAGEL treatment for you. This will depend on your health, if you take other medications, and how you respond to RENAGEL. Your total daily dose should be divided by your healthcare professional according to your meal portions during the day.

**Overdose:**

If you think you, or a person you are caring for, have taken too much RENAGEL, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you miss or forget to take a dose, skip the missed dose, and take your normal dose when the next one is due. Do NOT take a double dose to make up for the missed dose.

**What are possible side effects from using RENAGEL?**

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

Side effects of RENAGEL may include:

- anorexia,
- chest pain,
- constipation (if your constipation worsens or becomes severe, contact your healthcare professional),
- common cold,
- cough,
- diarrhea,
- fatigue,
- fever,
- headache,
- itch,
- nausea,
- rash,
- swollen abdomen,
- upset stomach,
- vomiting.

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	
UNCOMMON			
<b>Bowel perforation</b> (a hole in the wall of your stomach or bowels): severe abdominal pain and tenderness, nausea, vomiting, chills, or fever, bleeding (blood in stools)			✓
<b>Bowel blockage or obstruction</b> (blockage that stops or impairs passage of contents of intestines):			✓

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	
cramping pain in abdomen that may begin suddenly, bloating, loss of appetite, pain that comes and goes but will then last, nausea, vomiting, constipation, or diarrhea cramping and gas pains excessive burping			
<b>Dysphagia:</b> difficulty swallowing or problems with the esophagus.	✓		
<b>UNKNOWN FREQUENCY</b>			
<b>Allergic reactions:</b> rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing, difficulty breathing, itchiness, abdominal pain, redness of skin, wheezing, drop in blood pressure, nausea, or vomiting.			✓
<b>Diverticulitis</b> (inflammation of small pouches in the intestine): left lower quadrant pain, fever, nausea, diarrhea, or constipation.		✓	
<b>Inflammation of the bowel / peritonitis</b> (thin layer of tissue inside the abdomen becomes inflamed): severe abdominal pain, stomach or intestine problems, or blood in the stool.		✓	

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 healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### Storage:

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

Keep out of reach and sight of children.

### If you want more information about RENAGEL:

- 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](http://www.sanofi.ca)), or by calling 1-800-265-7927.

This leaflet was prepared by sanofi-aventis Canada Inc.

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