

## **PATIENT MEDICATION INFORMATION**

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

#### **PrACCEL-SEVELAMER**

#### **Sevelamer carbonate tablets**

Read this carefully before you start taking ACCEL-SEVELAMER 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 ACCEL-SEVELAMER.

#### **Serious Warnings and Precautions**

ACCEL-SEVELAMER may cause serious side effects that may require hospitalization and surgery. These serious side effects include:

- **Dysphagia** (difficulty swallowing, problems with esophagus)
- **Bowel Obstruction (ileus), Intestinal Blockage, or hole in the intestine**

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 ACCEL-SEVELAMER used for?**

ACCEL-SEVELAMER is used to lower high blood levels of phosphate in adults who:

- have end-stage kidney disease, and
- are undergoing dialysis.

#### **How does ACCEL-SEVELAMER work?**

ACCEL-SEVELAMER is a phosphate binder that is not absorbed in your body. When taken with meals, ACCEL-SEVELAMER binds with the phosphate in the food you ingested and prevents its absorption into your blood. This helps to lower the levels of phosphate in your body.

#### **What are the ingredients in ACCEL-SEVELAMER?**

Medicinal ingredients: Sevelamer carbonate

Non-medicinal ingredients: Colloidal anhydrous silica, diacetylated monoglycerides, hypromellose, lactose monohydrate, zinc stearate.

#### **ACCEL-SEVELAMER comes in the following dosage forms:**

Tablets: 800 mg

**Do not use ACCEL-SEVELAMER if:**

- you have abnormally low levels of phosphate in your blood
- you currently have gastrointestinal problems such as:
  - bowel obstruction
  - damage to the lining of the digestive tract caused by tissue death, holes or ulcers (sores)
  - gastrointestinal bleeding
- you are allergic to sevelamer carbonate or to any other ingredients in ACCEL-SEVELAMER. ACCEL-SEVELAMER contains lactose.

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

- have difficulty swallowing. This includes 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 abnormally low levels of phosphate or calcium in your blood.
- are pregnant, think you may be pregnant, or are planning to become pregnant.
- are breast feeding.
- are taking medicines used to control seizures or epilepsy.
- are taking medicines used to treat heart rhythm problems (arrhythmia).

**Other warnings you should know about:**

**Inflammation of the bowel:** ACCEL-SEVELAMER may cause serious bowel inflammation. This can lead to other serious complications such as:

- gastrointestinal bleeding
- damage to the lining of the digestive tract caused by tissue death, holes or ulcers (sores)
- tumours in the intestines
- chronic inflammation of the lining of the digestive tract

See the Serious side effects and what to do about them table, below, for more information on this and other serious side effects.

**Pregnancy:** Only take ACCEL-SEVELAMER during pregnancy if you and your healthcare professional have discussed the risks and have decided that you should.

**Breastfeeding:** The effects of ACCEL-SEVELAMER on breast milk and the breastfed baby are not well studied. Talk to your healthcare professional about the best way to feed your baby if you take ACCEL-SEVELAMER.

**Check-ups and testing:** Your healthcare professional may do blood tests before you start ACCEL-SEVELAMER and/or during your treatment. These tests will check:

- the amount of calcium, phosphate, bicarbonate and chloride in your blood
- the levels of vitamin D, E, K and folic acid in your blood.

Depending on your test results, your healthcare professional may tell you to take supplements during your treatment with ACCEL-SEVELAMER.

**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 ACCEL-SEVELAMER:**

- Ciprofloxacin – used to treat bacterial infections
- Cyclosporin, mycophenolate, tacrolimus – used to prevent rejection of organ transplants
- Levothyroxine – used to treat an underactive thyroid gland
- Proton pump inhibitors, such as omeprazole, lansoprazole, pantoprazole – used to relieve symptoms of acid reflux and treat stomach ulcers

Some medicines may need to be taken one hour before or three hours after taking ACCEL-SEVELAMER. Your healthcare professional will give you instructions on how to take your other medications when treated with ACCEL-SEVELAMER.

**How to take ACCEL-SEVELAMER:**

- Swallow the tablets **whole**. **DO NOT** crush, chew, or break the tablet.
- Tablets should **ONLY** be taken with meals or snacks. You **SHOULD NOT** take it on an empty stomach.
- ACCEL-SEVELAMER should be taken 3 times a day with meals and / or snacks.
- The total daily dose the healthcare professional tells you to take should be divided between the meals or snacks portions you eat during the day.

**Usual dose:**

Your healthcare professional will:

- determine your dose based on the phosphate levels in your blood.
- monitor your phosphate levels and change the dose as needed.

Take ACCEL-SEVELAMER exactly as directed by your healthcare professional.

**Overdose:**

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

**Missed Dose:**

If you forget to take a dose, skip it and take the next dose as scheduled. Do not double the dose.

**What are possible side effects from using ACCEL-SEVELAMER?**

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

<b>Serious side effects and what to do about them</b>			
<b>Symptom / effect</b>	<b>Talk to your healthcare professional</b>		<b>Stop taking drug and get immediate medical help</b>
	<b>Only if severe</b>	<b>In all cases</b>	
<b>COMMON</b>			
Abdominal pain.		✓	
<b>RARE</b>			
<b>Allergic reactions:</b> difficulty swallowing or breathing, wheezing; drop in blood pressure; feeling sick to your stomach and throwing up; hives or rash; swelling of the face, lips, tongue or throat.			✓
<b>Bowel Obstruction (ileus), Intestinal Blockage, or hole in the intestine:</b> 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.			✓
<b>Diverticulitis:</b> pain and tenderness in the left lower part of the abdomen, fever, nausea, diarrhea, or constipation.		✓	
<b>Dysphagia:</b> Difficulty swallowing, problems with your esophagus.	✓		

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	
<b>Inflammation of the bowel:</b> Severe abdominal pain, stomach or intestine problems, 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.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 tablets between 15°C to 30°C.
- Protect from moisture and heat.
- Keep out of reach and sight of children.

### If you want more information about ACCEL-SEVELAMER:

- 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 <http://www.accelpharma.com>, or by calling 1-877-822-2235.

This leaflet was prepared by Accel Pharma Inc.

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