

PART III: CONSUMER INFORMATION

PrREVELA®

Sevelamer Carbonate Tablets and Sevelamer Powder for Oral Suspension

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

ABOUT THIS MEDICATION

What the medication is used for:

REVELA is used to treat high levels of phosphorus in the blood in the following patients who have end-stage renal disease and are undergoing dialysis:

- adults and
- children (6 years of age and older) with a Body Surface Area (BSA) of equal to or greater than 0.75 m²

What it does:

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

When it should not be used:

- in patients with low 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 carbonate or one of the other ingredients in the product (See What the nonmedicinal ingredients are).
- in children that are below 6 years of age, have a BSA less than 0.75 m², or that have mild hyperphosphatemia.

What the medicinal ingredient is:

Sevelamer carbonate

What the nonmedicinal ingredients are

Tablets: Diacetylated monoglycerides, hypromellose, microcrystalline cellulose, sodium chloride, zinc stearate.

Powder: Natural and artificial citrus cream flavouring, propylene glycol alginate, sodium chloride, sucralose, and ferric oxide (yellow).

What dosage forms it comes in:

Tablets: 800 mg

Powder: 0.8 g and 2.4 g

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

REVELA 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, bowel perforation.

BEFORE you use RENVELA 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

REVELA 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 RENVELA. Remember, RENVELA must always be taken with food.

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

Drugs that may interact with RENVELA 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 RENVELA.

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

REVELA 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

Tablets and Powder

REVELA is available as tablets or powder for oral suspension. The powder should be used if you:

- have trouble swallowing the tablets. Talk to your doctor about which one you prefer to take. You can switch between the tablets and powder over the course of your treatment. However you **SHOULD NOT** mix a tablet and the powder together to get your dose.
- will be giving REVELA to a small child
- REVELA should be taken 3 times a day with meals and/or snacks.
- It should **ONLY** be taken or given to your child with meals or snacks. You **SHOULD NOT** take it or give it to your child on an empty stomach.
- The total daily dose the doctor tells you to take should be divided between the meals or snacks portions you or your child eats during the day.

Tablet: Swallow the tablets **whole**. **DO NOT** crush, chew or break the tablet.

Powder: Before you can take the powder, it must be mixed:

- in water or (see A))
- in a drink other than water such as ginger ale (see A)) or
- sprinkled on food such as applesauce, whey protein powder or added to lukewarm foods after cooking (up to 50°C) such as oatmeal, scrambled eggs and baked boneless-skinless chicken breast (see B))

More than one sachet can be taken at the same time as long as the minimum amount of water or food is used for each sachet.

The powder **DOES NOT** dissolve. It should be stirred vigorously just before you or your child drinks it.

Once mixed in water or a drink or added to food, it should be taken within 30 minutes. It is important to drink all of the liquid or eat the entire food to ensure that all of the powder is taken.

DO NOT:

- take REVELA as a dry powder or
- heat the powder (put it in the microwave or other heat source) or
- add it to hot foods or liquids

Usual starting dose:

Your doctor will:

- determine your dose based on your phosphorus levels
- determine your child’s dose based on their Body Surface Area
- monitor your and your child’s phosphorus levels and change the dose as needed

Take it exactly as directed by your doctor.

Instructions on How to Use the Powder:

REVELA is only available in 0.8 g and 2.4 g sachets.

Before opening the sachets:

- hold the top corner of the sachet and shake it to move the powder to the bottom
- open it by tearing along the marked line

A) How to prepare a dose in water or in a drink other than water such as ginger ale

| Strength | Minimum amount of liquid to be mixed for each sachet | |
|------------------------------|--|------------|
| | mL | tablespoon |
| 0.8 g (use entire sachet) | 30 | 2 |
| 2.4 g (use entire sachet) | 60 | 4 |

B) How to prepare a dose when added to food

| Strength | Minimum amount of food to be used for each sachet | |
|------------------------------|---|-------------|
| | mL | tablespoons |
| 0.8 g (use entire sachet) | 120 | 8 |
| 2.4 g (use entire sachet) | 120 | 8 |

In some cases, your doctor may recommend 0.4 g dose adjustments for your child to get the correct dose. Since REVELA is not available in a 0.4 g sachet, you will need to measure some powder from a 0.8 g sachet to get the 0.4 g dose (see C) and D)).

C) How to measure 0.4 g of powder from a 0.8 g sachet

Use a measuring spoon to measure the correct amount of powder for your 0.4 g dose. DO NOT tap the measuring spoon to compact the powder.

| Strength | Amount of powder to be taken from a 0.8 g sachet |
|----------|--|
| 0.4 g | 1 mL or ¼ teaspoon |

- Close the 0.8 g sachet by folding it over twice

- The remaining powder may be used within 24 hours for the next dose
- Throw away the sachet if it has been left opened for more than 24 hours and use a new one.

D) How to prepare a 0.4 g dose in water or in a drink other than water such as ginger ale or if added to food

| Strength | Minimum amount of liquid to be mixed | | Minimum amount of food to be used | |
|----------|--------------------------------------|-------------|-----------------------------------|-------------|
| | mL | tablespoons | mL | tablespoons |
| 0.4 g | 30 | 2 | 120 | 8 |

Overdose:

In case of an overdose, contact your doctor or regional 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 RENEVELA is generally well tolerated, some patients may experience side effects, including: nausea, vomiting, diarrhea, indigestion, constipation, abdominal pain, rash, itch, and flatulence (gas). Tell your doctor if you have new onset or worsening of constipation.

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 RENEVELA.

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 Frequency | | | |
| 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 RENEVELA, contact your doctor or pharmacist.

HOW TO STORE IT

Store the tablets and powder at controlled room temperature 15°C to 30°C. Protect from moisture and heat.

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

MORE INFORMATION

If you want more information about RENVELA:

- Talk to your healthcare professional.
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Consumer 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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