Consilient Health

PACKAGE LEAFLET: INFORMATION FOR THE USER

Sevelamer carbonate 2.4 g powder for oral suspension

sevelamer carbonate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. WHAT SEVELAMER IS AND WHAT IT IS USED FOR

Sevelamer contains sevelamer carbonate as the active substance. It binds phosphate from food in the digestive tract and so reduces serum phosphorus levels in the blood.

This medicine is used to control hyperphosphataemia (high blood phosphate levels) in:
- adult patients on dialysis (a blood clearance technique). It can be used in patients undergoing haemodialysis (using a blood filtration machine) or peritoneal dialysis (where fluid is pumped into the abdomen and an internal body membrane filters the blood);
- adult patients with chronic (long-term) kidney disease who are not on dialysis and have a serum (blood) phosphorus level equal to or above 1.78 mmol/l.
- paediatric patients with chronic (long-term) kidney disease above the age of 6 and above a certain height and weight (used to calculate body surface area by your physician).

This medicine should be used with other treatments such as calcium supplements and vitamin D to prevent the development of bone disease.
Increased levels of serum phosphorus can lead to hard deposits in your body called calcification. These deposits can stiffen your blood vessels and make it harder for blood to be pumped around the body. Increased serum phosphorus can also lead to itchy skin, red eyes, bone pain and fractures.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SEVELAMER

Do not take Sevelamer if:
- you are **allergic to the active substance or to any of the other ingredients** of this medicine (listed in section 6).
- you have **low levels of phosphate** in your blood (your doctor will check this for you)
- you have **bowel obstruction**

Warnings and precautions

Talk to your doctor before taking Sevelamer if any of the following applies to you:
- problems with **motility (movement) in your stomach and bowel**
- **being sick** frequently
- active **inflammation of the bowel**
- have undergone **major surgery** on your stomach or bowel.
- serious inflammatory bowel disease.

Talk to your doctor while taking Sevelamer:
- if you experience severe abdominal pain, stomach or intestine disorders, or blood in the stool (gastrointestinal bleeding). These symptoms can be due to sevelamer crystals deposit in your bowel. Contact your doctor who will decide on continuing the treatment or not.

Additional treatments:
Due to either your kidney condition or your dialysis treatment you may:
- develop low or high levels of calcium in your blood. Since this medicine does not contain calcium your doctor might prescribe additional calcium tablets.
- have a low amount of vitamin D in your blood. Therefore, your doctor may monitor the levels of vitamin D in your blood and prescribe additional vitamin D as necessary. If you do not take multivitamin supplements you may also develop low levels of vitamins A, E, K and folic acid in your blood and therefore your doctor may monitor these levels and prescribe supplemental vitamins as necessary.
- have disturbed level of bicarbonate in your blood and increased acidity in the blood and other body tissue. Your doctor should monitor the level of bicarbonate in your blood.

Special note for patients on peritoneal dialysis:
You may develop peritonitis (infection of your abdominal fluid) associated with your peritoneal dialysis. This risk can be reduced by careful adherence to sterile techniques during bag changes. You should tell your doctor immediately if you experience any new signs or symptoms of abdominal distress, abdominal swelling, abdominal pain, abdominal tenderness, or abdominal rigidity, constipation, fever, chills, nausea or vomiting.

Children

The safety and efficacy in children (below the age of 6 years) have not been studied. Therefore this medicine is not recommended for use in children below the age of 6 years.

Other medicines and Sevelamer

Tell your doctor if you are taking or have recently taken or might take any other medicines.
- Sevelamer should not be taken at the same time as **ciprofloxacin (an antibiotic)**.
- If you are taking **medicines for heart rhythm problems or for epilepsy**, you should consult your doctor when taking Sevelamer.
- The effects of medicines such as ciclosporin, mycophenolate mofetil and tacrolimus (**medicines used to suppress the immune system**) may be reduced by Sevelamer. Your doctor will advise you if you are taking these medicines.
- Thyroid hormone deficiency may uncommonly be observed in certain people taking **levothyroxine** (**used to treat low thyroid hormone levels**) and Sevelamer. Therefore your doctor may monitor the levels of thyroid stimulating hormone in your blood more closely.
- Medicines treating heartburn and reflux from your stomach or oesophagus such as omeprazole, pantoprazole, or lansoprazole, known as “proton pump inhibitors”, may reduce the efficacy of Sevelamer. Your doctor may monitor the phosphate level in your blood.

Your doctor will check for interactions between sevelamer and other medicines on a regular basis.
In some cases where sevelamer should be taken at the same time as another medicine, your doctor may advise you to take this medicine 1 hour before or 3 hours after sevelamer intake. Your doctor may also consider monitoring the levels of that medicine in your blood.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. The potential risk of Sevelamer during human pregnancy is unknown. Talk to your doctor who will decide if you can continue the treatment with Sevelamer.
It is unknown whether sevelamer is excreted in breast milk and may affect your baby. Talk to your doctor who will decide if you can breastfeed your baby or not, and if it is necessary to stop Sevelamer treatment.

Driving and using machines

Sevelamer is unlikely to affect your ability to drive or to use machines.

Excipients

This medicine contains less than 1 mmol sodium (23 mg) per sachet, that is to say essentially ‘sodium-free’.

3. HOW TO TAKE SEVELAMER

You must take sevelamer as prescribed by your doctor. They will base the dose on your serum phosphorus level.
For a 2.4 g dose, the powder for oral suspension should be dispersed in 60 ml of water per sachet. Drink within 30 minutes of being prepared. It is important to drink all of the liquid and it may be necessary to rinse the glass with water and drink this as well to ensure that all of the powder is swallowed. Instead of water, the powder may be pre-mixed with a small amount of cold beverage (about 120 ml or half a glass) or food (about 100 grams) and consumed within 30 minutes. Do not heat Sevelamer powder (e.g. microwave) or add to hot foods or liquids.
The recommended starting dose of this medicine for adults and elderly is 2.4-4.8g per day equally divided over three meals. The exact starting

dose and regimen will be determined by your doctor. Check with your doctor, pharmacist or nurse if you are not sure.
Take Sevelamer after your meal or with food.

Use in children and adolescents
The recommended starting dose of Sevelamer for children is based on their height and weight (used to calculate body surface area by your physician). For children, the powder is preferred, as tablets are not appropriate in this population. This medicine should not be given on an empty stomach and should be taken with meals or snacks. The exact starting dose and regimen will be determined by your doctor.

For doses of less than 2.4 g, the powder in the sachet may be divided. The Sevelamer powder may be measured by volume (mL) using a measuring scoop or measuring spoon.

Sevemaler carbonate dose (g)	Volume (mL)
0.4 g (400 mg)	1.0 mL
0.8 mg (800 mg)	2.0 mL
1.2 g (1200 mg)	3.0 mL
1.6 g (1600 mg)	4.0 mL

Preparation using a 1 mL measuring scoop:
For a 0.4 g dose:
Due to either your kidney condition or your dialysis treatment you may:
- Open the sachet by tearing along the marked line.
- Insert the scoop into the sachet.
- Fill the scoop above the top edge.
- Withdraw the scoop from the sachet using the top edge of the open sachet to level the powder with the top of the scoop. This allows excess powder to fall back into the sachet.
- Disperse the 1.0 mL of the powder from the measuring scoop in 60 mL of water. Drink within 30 minutes of being prepared. It is important to drink all of the liquid to ensure that all of the powder is swallowed.
- Close the sachet by folding over twice.
- The remaining powder may be used within 24 hours for the next dose.
- Discard sachets of powder that have been opened for more than 24 hours.

For a 0.8 g dose: Follow the instructions above, filling the scoop twice for a total of 2.0 mL powder.

For a 1.2 g dose: Follow the instructions above, filling the scoop three times for a total of 3.0 mL powder.

For a 1.6 g dose: Follow the instructions above, filling the scoop four times for a total of 4.0 mL powder.

Preparation using a measuring spoon
For a 0.4 g dose:
Due to either your kidney condition or your dialysis treatment you may:
- Open the sachet by tearing along the marked line.
- Hold the measuring spoon vertically.
- Pour the contents of the sachet into the measuring spoon to fill the spoon to 1.0 mL.
- Do not tap the dosing spoon to compact the powder.
- Disperse the 1.0 mL of the powder from the measuring spoon in 60 mL of water. Drink within 30 minutes of being prepared. It is important to drink all of the liquid to ensure that all of the powder is swallowed.
- Close the sachet by folding over twice.
- The remaining powder may be used within 24 hours for the next dose.
- Discard sachets of powder that have been opened for more than 24 hours.

For a 0.8 g dose: Follow the instructions above, filling the spoon twice for a total of 2.0 mL powder.

For a 1.2 g dose: Follow the instructions above, filling the spoon three times for a total of 3.0 mL powder.

For a 1.6 g dose: Follow the instructions above, filling the spoon four times for a total of 4.0 mL powder.

Initially, your doctor will check the levels of phosphorus in your blood every 2-4 weeks and they may adjust the dose of sevelamer when necessary to reach an adequate phosphate level.
Follow the diet prescribed by your doctor.

If you take more Sevelamer than you should
In the event of a possible overdose you should contact your doctor immediately.

If you forget to take Sevelamer
If you have missed one dose, this dose should be omitted and the next dose should be taken at the usual time with a meal. Do not take a double dose to make up for a forgotten dose.

If you stop taking Sevelamer
Taking your Sevelamer treatment is important to maintain an appropriate phosphate level in your blood. Stopping Sevelamer would lead to important consequences such as calcification in the blood vessels. If you consider stopping your Sevelamer treatment, contact your doctor or pharmacist first. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS
Like all medicines, this medicine can cause side effects, although not everybody gets them.

Constipation is a very common side effect (may affect more than 1 in 10 people). It can be an early symptom of a blockage in your intestine. In case of constipation, please inform your doctor or pharmacist.

Some side effects could be serious. If you get any of the following side effects, seek immediate medical attention:

- Allergic reaction (signs including rash, hives, swelling, trouble breathing). This is a very rare side effect (may affect up to 1 in 10,000 people).
- Blockage in the intestine (signs include: severe bloating; abdominal pain, swelling or cramps; severe constipation) has been reported.

Frequency is not known (frequency cannot be estimated from the available data).
- Rupture in the intestinal wall (signs include: severe stomach pain, chills, fever, nausea, vomiting, or a tender abdomen) has been reported. Frequency is not known.
- Intestinal bleeding, inflammation of the large bowel and crystal deposit in the intestine have been reported. Frequency not known.

Other side effects have been reported in patients taking sevelamer:

Very common (may affect more than 1 in 10 people)
• Vomiting • Upper abdominal pain • Nausea

Common (may affect up to 1 in 10 people)
• Diarrhoea • Stomach ache • Indigestion • Flatulence

Not known (frequency cannot be estimated from the available data)
• Cases of itching • Rash • Slow intestine motility (movement)

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE SEVELAMER
Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date stated on the sachet and carton after the letters “EXP”.
The medicinal product does not require any special storage conditions.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 CONTENTS OF THE PACK AND OTHER INFORMATION
What Sevelamer contains
- The active substance is sevelamer carbonate. Each sachet contains 2.4 g of sevelamer carbonate.
- The other ingredients ingredients are microcrystalline cellulose (E460), carmellose sodium, sucralose (E955), lemon flavour, orange flavour and iron oxide yellow (E172).

What Sevelamer looks like and contents of the pack
Sevelamer powder for oral suspension is an off-white to yellow powder supplied in a foil sachet. The foil sachets are packaged in an outer carton.

Pack sizes: 60 sachets per carton, 90 sachets per carton
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Consilient Health Ltd.,
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