



Package leaflet: Information for the user

Sevelamer carbonate 800 mg film-coated tablets

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 further questions, ask your doctor or your 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. 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
2. What you need to know before you take Sevelamer
3. How to take Sevelamer
4. Possible side effects
5. How to store Sevelamer
6. Contents of the pack and other information

1. What Sevelamer is and what it is used for

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

Sevelamer 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);
- 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.

Sevelamer 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 have low levels of phosphate in your blood (your doctor will check this for you)
- you have bowel obstruction
- you are allergic to the active substance or to any of the other ingredients of this medicine (listed in section 6).

Warnings and Precautions

Talk to your doctor before taking Sevelamer if any of the following applies to you:

- swallowing problems
- 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

Children and adolescents

The safety and efficacy in children (below the age of 18 years) has not been established. Therefore Sevelamer is not recommended for use in children.

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 sevelamer carbonate 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.

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. You should expect to be monitored more carefully for problems with low levels of vitamins A, D, E, K and folic acid.

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 cyclosporin, 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.

If you are taking medicine to treat heartburn, gastroesophageal reflux disease (GERD) or gastric ulcers, such as omeprazole, prantoprazole, or lansoprazole, you should consult your doctor when taking Sevelamer.

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, or they may consider monitoring the blood levels of that medicine.

Sevelamer with food and drink

You must take Sevelamer tablets with meals.

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. It is unknown whether Sevelamer has any effect on unborn babies.

Tell your doctor if you wish to breast-feed your baby. It is unknown whether Sevelamer may pass through breast milk and affect your baby.

Driving and using machines

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

Sevelamer contains lactose

Sevelamer contains lactose (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Sevelamer

You must take Sevelamer as prescribed by your doctor. They will base the dose on your serum phosphorus level.

The recommended starting dose of Sevelamer tablets for adults and the elderly (> 65 years) is one to two tablets of 800 mg with each meal, 3 times a day.

The tablets must be swallowed whole. Do not crush, chew or break into pieces.

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

Patients taking Sevelamer should adhere to their prescribed diets.

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.

4. Possible side effects

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

Since constipation may be an early symptom of a blockage in your intestine, please inform your doctor or pharmacist.

The following side effects have been reported in patients taking Sevelamer:

Very common (may affect more than 1 in 10 people):
vomiting, constipation, upper abdominal pain, nausea

Common (may affect up to 1 in 10 people):
diarrhoea, abdominal pain, indigestion, flatulence

Very rare (may affect up to 1 in 10000 people):
hypersensitivity

Not known (frequency cannot be estimated from the available data):
cases of itching, rash, slow intestine motility (movement)/blockages in the intestine, and perforation in the intestine wall have been reported.

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 MHRA 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 bottle and carton after the letters "EXP". The expiry date refers to the last day of that month.

This 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 tablet contains 800 mg of sevelamer carbonate.
- The other ingredients are lactose monohydrate, silica (colloidal anhydrous), zinc stearate. The tablet coating contains hypromellose (E464) and diacetylated monoglycerides.

What Sevelamer looks like and contents of the pack

Sevelamer are oval, white to off-white film-coated tablets with the inscription 'SVL' on one side.

HDPE bottles with a polypropylene cap.
Each bottle contains 180, 200 or 210 tablets.
Packs containing 1, 2 or 3 bottles are available.

The HDPE bottles contain a desiccant. Do not remove this desiccant from the bottle.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder:
Amneal Pharma Europe Limited
70 Sir John Rogerson's Quay
Dublin 2
Ireland

Manufacturer:
Synthon Hispania SL.
C/Castello No.1,
Pol. Las Salinis,
Sant boi de Llobregat,
Barcelona, 08830,
Spain

This leaflet was last revised in February 2017