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 you doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Sevelamer carbonate is and what it is used for
2. What you need to know before you take Sevelamer carbonate
3. How to take Sevelamer carbonate
4. Possible side effects
5. How to store Sevelamer carbonate
6. Contents of the pack and other information

1. What Sevelamer carbonate is and what it is used for

Sevelamer carbonate 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 carbonate 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 carbonate 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 carbonate

Do not take Sevelamer carbonate 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 carbonate if any of the following applies to you:

- **swallowing** problems. Your doctor can prescribe a powder for oral suspension
- 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.
- if you have serious inflammatory bowel disease.

Talk to your doctor while taking Sevelamer carbonate:

- if you experience severe abdominal pain, stomach or intestine disorders, or blood in your stools (gastrointestinal bleeding). These symptoms can be due to sevelamer crystal deposits 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 carbonate

Tell your doctor if you are taking, have recently taken or might take any other medicines:

- Sevelamer carbonate 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 carbonate.
- The effects of medicines such as ciclosporin, mycophenolate mofetil and tacrolimus **(medicines used to suppress the immune system)** may be reduced by Sevelamer carbonate. 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 treatment low thyroid hormone levels) and Sevelamer carbonate. 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 effectiveness of Sevelamer carbonate. Your doctor may monitor the phosphate level in your blood.

Your doctor will check for interactions between Sevelamer carbonate and other medicines on a regular basis.

In some cases where Sevelamer carbonate 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 carbonate. 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 carbonate during human pregnancy is unknown. Talk to your doctor who will decide if you can continue the treatment with Sevelamer carbonate.

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VIATRIS					
Description	Sevelamer carbonate,800 mg, 180			Date: 30 JAN 2024	Time: 19:00
Component Type	Leaflet/IFU - Folded	Site Barcode/ DataMatrix	9891	No. of colours: 1	Page Count: 1 of 2
Affiliate Item Code	ART-49561-01	Viatris SAP No.	400524215	Colours: Black	
Superseded Affiliate Item Code	N.A.	Vendor Job No.	N.A.		
TrackWise/GLAMS Job No.	ART-49561-01	Artwork Proof No.	1	Non-Print Colours: Keyline	
MA No.	PL 04569/1623	Client Market	United Kingdom	Equate CMYK with	
Supplier SAP No.	N.A.	Barcode Info	N.A.	Main Font: Myriad Pro	Body Text Size: 10 pt
New Supplier Code	1703-M.2001	3D Render ID	N.A.	Dimensions: 200x320 mm	Min Text Size used: 10 pt
Superseded Supplier Code	N.A.			Keyline/Drawing No.: 09062021B	
Packing Site/Printer	GE Pharmaceuticals Ltd (Botevgrad - BG)				
Sign-offs					
					V3 MAY 2023

It is unknown whether Sevelamer carbonate 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 carbonate treatment.

Driving and using machines
Sevelamer carbonate is unlikely to affect your ability to drive or to use machines.

Sevelamer carbonate contains lactose
Sevelamer carbonate 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 medicine.

3. How to take Sevelamer carbonate

You must take Sevelamer carbonate as prescribed by your doctor. They will base the dose on the level of phosphorus in your blood.

The recommended starting dose of Sevelamer carbonate tablets for adults and the elderly (> 65 years) is **one to two tablets of 800 mg with each meal, 3 times a day.** Check with your doctor, pharmacist or nurse if you are not sure.

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 carbonate when necessary to reach an adequate phosphate level.

Patients taking Sevelamer carbonate should adhere to their prescribed diets.

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

If you forget to take Sevelamer carbonate
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 carbonate
Taking your Sevelamer carbonate treatment is important to maintain an appropriate phosphate level in your blood. Stopping Sevelamer carbonate would lead to important consequences such as calcification in the blood vessels. If you consider stopping your 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.

Tell your doctor or pharmacist as soon as possible if you experience the following:

Very common (may affect more than 1 in 10 people):
- constipation, which may be an early sign of a blockage in your intestine

Very rare (may affect up to 1 in 10,000 people):
- severe allergic reactions, including swelling of the face, lips, tongue or throat, causing difficulty breathing or swallowing.

Not known (frequency cannot be estimated from the available data):
- cases of itching, rash, slow intestine mobility (movement), blockages in the intestine (signs include severe bloating, abdominal pain, swelling or cramps; severe constipation), rupture in the intestine wall (signs include: severe stomach pain, chills, fever, nausea, vomiting, or a tender abdomen), intestinal bleeding, inflammation of the large bowel and crystal deposit in the intestine have been reported.

Other side effects reported in patients taking sevelamer carbonate:

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
- abdominal pain
- indigestion
- flatulence.

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 Yellow Card Scheme at: ww.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 carbonate

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 carbonate 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 carbonate looks like and contents of the pack

Sevelamer carbonate 800 mg film-coated tablets are white to off-white, oval shaped tablets and are marked with 'SVL' on one side. The tablets are approximately 20 mm long and 7 mm wide.

The tablets are packed in high density polyethylene bottles with a polypropylene cap. Each bottle contains 180, 200 or 210 tablets. Packs containing 1, 2 or 3 bottles are available.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan,
Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.

Manufacturer

Synthon Hispania SL,
Castelló 1, Polígono Las Salinas,
08830 Sant Boi de Llobregat,
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Mylan Hungary Kft.,
H-2900 Komárom,
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10/2019

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VIATRIS				Date: 30 JAN 2024		Time: 19:00	
Description	Sevelamer carbonate,800 mg, 180			No. of colours	1	Page Count	2 of 2
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Superseded Affiliate Item Code	N.A.	Vendor Job No.	N.A.	Equate CMYK with			
TrackWise/GLAMS Job No.	ART-49561-01	Artwork Proof No.	1	Main Font	Myriad Pro	Body Text Size	10 pt
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New Supplier Code	1703-M.2001	3D Render ID	N.A.				
Superseded Supplier Code	N.A.						
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