Consilient Health

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 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 carbonate 800 mg film-coated tablets is and what it is used for
2. What you need to know before you take Sevelamer carbonate 800 mg film-coated tablets
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1. WHAT SEVELAMER CARBONATE 800 MG FILM-COATED TABLETS ARE AND WHAT IT IS USED FOR

Sevelamer carbonate 800 mg film-coated tablets 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);
- 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.

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 CARBONATE 800 MG FILM-COATED TABLETS

Do not take Sevelamer carbonate 800 mg film-coated tablets 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 800 mg film-coated tablets if any of the following applies to you:
- **swallowing** problems. Your doctor can rather prescribe sevelamer carbonate as 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.

Talk to your doctor while taking Sevelamer carbonate 800 mg film-coated:
- if you experience severe abdominal pain, stomach or intestine disorders, or blood in the stool (gastrointestinal bleeding). These symptoms can be due to serious inflammatory bowel disease caused by 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 carbonate 800 mg film-coated tablets

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

- Sevelamer carbonate 800 mg film-coated tablets 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 800 mg film-coated tablets.
- The effects of medicines such as **ciclosporin, mycophenolate mofetil** and **tacrolimus** (medicines used to suppress the immune system) may be reduced by Sevelamer carbonate 800 mg film-coated tablets. 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 carbonate 800 mg film-coated tablets. 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 carbonate 800 mg film-coated tablets.. Your doctor may monitor the phosphate level in your blood.

Your doctor will check for interactions between Sevelamer carbonate 800 mg film-coated tablets and other medicines on a regular basis.

In some cases where Sevelamer carbonate 800 mg film-coated tablets 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 800 mg film-coated tablets 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 carbonate 800 mg film-coated tablets during human pregnancy is unknown. Talk to your doctor who will decide if you can continue the treatment with Sevelamer carbonate 800 mg film-coated tablets.

It is unknown whether Sevelamer carbonate 800 mg film-coated tablets 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 800 mg film-coated tablets treatment.

Driving and using machines

Sevelamer carbonate 800 mg film-coated tablets is unlikely to affect your ability to drive or to use machines.

Sevelamer carbonate 800 mg film-coated tablets contains lactose

Sevelamer carbonate 800 mg film-coated tablets 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 CARBONATE 800 MG FILM-COATED TABLETS

You must take Sevelamer carbonate 800 mg film-coated tablets as prescribed by your doctor. They will base the dose on your serum phosphorus level.

The recommended starting dose of Sevelamer carbonate 800 mg film-coated tablets tablets for adults and the elderly 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.

Take Sevelamer carbonate 800 mg film-coated tablets after your meal or with food. **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 they may adjust the dose of Sevelamer carbonate 800 mg film-coated tablets when necessary to reach an adequate phosphate level.

Follow the diets prescribed by your doctor.

If you take more Sevelamer carbonate 800 mg film-coated tablets than you should
In the event of a possible overdose you should contact your doctor immediately.

If you forget to take Sevelamer carbonate 800 mg film-coated tablets
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 800 mg film-coated tablets
Taking your Sevelamer carbonate 800 mg film-coated tablets treatment is important to maintain an appropriate phosphate level in your blood.
Stopping Sevelamer carbonate 800 mg film-coated tablets would lead to important consequences such as calcification in the blood vessels. If you consider stopping your Sevelamer carbonate 800 mg film-coated tablets 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.
- Serious inflammation of the large bowel (symptoms include: severe abdominal pain, stomach or intestine disorders, or blood in the stool [gastrointestinal bleeding]) and crystal deposit in the intestine have been reported. Frequency is not known.

Other side effects have been reported in patients taking Sevelamer carbonate 800 mg film-coated tablets:

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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE SEVELAMER CARBONATE 800 MG FILM-COATED TABLETS

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 800 mg film-coated tablets contain
- The active substance is sevelamer carbonate. Each Sevelamer carbonate 800 mg film-coated 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 800 mg film coated tablets look like and contents of the pack
Sevelamer carbonate 800 mg film-coated tablets are oval, white to off-white film-coated tablets with the inscription 'SVL' on one side.
Pack sizes:
HDPE bottles with a polypropylene cap.
Each bottle contains 180, 200 or 210 tablets.
Packs containing 1, 2 or 3 bottles are available.

[Bottles containing a dessicant only]: 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:
Consilient Health Limited,
Floor 3, Block 3, Miesian Plaza,
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Manufacturer:
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This leaflet was last revised in 01/2024.