Sevelamer carbonate 800 mg film-coated tablets

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 this medicine?

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 phosphate levels in the blood.

Sevelamer is used to control hyperphosphataemia (high blood phosphate levels) in:
• Kidney patients on dialysis (a blood cleansing technique).
• Kidney patients on peritoneal dialysis (where fluid is pumped into the abdomen and an internal body membrane filters the blood).

Sevelamer should be used with other treatments such as calcium supplements and vitamin D to prevent the development of bone disease.

What you need to know before you take Sevelamer

2. What you need to know before you take Sevelamer

Tell your doctor if you are taking or have recently taken or might take any other medicines.
You must take Sevelamer tablets with meals.
You will need to monitor the blood levels of that medicine.

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 octreotide (an anti-diarrhoeal).
If you are taking medicines for heart rhythm problems or for epilepsy, you should consult your doctor when taking Sevelamer.

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.

Sevelamer carbonate does not contain calcium your doctor might prescribe additional calcium tablets.
Additional treatments:
Due to either your kidney condition or your dialysis treatment you may:
• develop low or high levels of calcium 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 folate. Sevelamer may also lead to low calcium, low vitamin D, E, K, and folate, which may affect your baby.
• 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 high 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 folate. Sevelamer may also lead to low calcium, low vitamin D, E, K, and folate, which may affect your baby.

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 if you develop signs of infection and follow any treatment prescribed for your peritonitis.

3. How to take Sevelamer

Sevelamer should be swallowed whole with a glass of water. Sevelamer should be taken with meals.

4. Possible side effects
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.

5. How to store Sevelamer

Sevelamer should be stored below 25°C in an open container.

6. Contents of the pack and other information

Sevelamer contains:
Sevelamer carbonate 800 mg film-coated tablets

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

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

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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 phosphorus level.

Sevelamer should be stored in the refrigerator during transport.

If you take more Sevelamer than you should

In the event of a possible overdose you should contact your doctor immediately.

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 intestines, please inform your doctor or pharmacist.

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

- Vomiting (may affect more than 1 in 10 people)
- Constipation (may affect 1 in 10 people)
- Diarrhoea (may affect 1 in 100 people)
- Abdominal pain
- Nausea
- Indigestion
- Flatulence

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.

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 medications you no longer use. These measures will help protect the environment.

This leaflet was last revised in February 2017