

Sevelamer carbonate Genthon 800

Sevelamer carbonate 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 in this leaflet

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1. What Sevelamer carbonate Genthon 800 mg film-coated tablet is and what it is used for

Sevelamer carbonate Genthon 800 mg film-coated tablets contain sevelamer carbonate as the active ingredient. It binds phosphate from food in the digestive tract and so reduces serum phosphorus levels in the blood.

Patients who have kidneys that do not work properly are not able to control the level of serum phosphorus in their blood. The amount of phosphate then rises (your doctor will call this hyperphosphatemia). 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 Genthon 800 mg film-coated tablets

Do not take Sevelamer carbonate Genthon 800 mg film-coated tablets 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 any of the other ingredients** of this medicine (listed in section 6)

Warnings and Precautions

Talk to your doctor before taking Sevelamer carbonate Genthon 800 mg film-coated tablets 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

The safety and efficacy in children (below the age of 18 years) has not been established. Therefore Sevelamer carbonate Genthon 800 mg film-coated tablets are 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 notes 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 carbonate Genthon 800 mg film-coated tablets

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

Sevelamer carbonate Genthon 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 Genthon 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 Genthon 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 treatment low thyroid hormone levels) and Sevelamer carbonate Genthon 800 mg film-coated tablets. Therefore your doctor may monitor the levels of thyroid stimulating hormone in your blood more closely.

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

Sevelamer carbonate Genthon 800 mg film-coated tablets with food and drink

You must take Sevelamer carbonate Genthon 800 mg film-coated tablets with meals.

Pregnancy, breast-feeding and fertility

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 carbonate Genthon 800 mg film-coated tablets have any effect on unborn babies.

Tell your doctor if you wish to breast-feed your baby. It is unknown whether Sevelamer carbonate Genthon 800 mg film-coated tablets may pass through breast milk and affect your baby.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed. If you are affected, do not drive and do not use any tools or machines.

Sevelamer carbonate Genthon 800 mg film-coated tablets contain lactose

Sevelamer carbonate Genthon 800 mg film-coated tablets contain 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 Genthon 800 mg film-coated tablets

You must take Sevelamer carbonate Genthon 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 Genthon 800 mg film-coated tablets for adults and the elderly (> 65 years) is **one to two tablets of 800 mg with meal, 3 times a day**.

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

In some cases **where Sevelamer carbonate Genthon 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 Genthon 800 mg film-coated tablet intake, or they may consider monitoring the blood levels of that medicine.

Your doctor will check the levels of phosphorus in your blood periodically and they may adjust the dose of Sevelamer carbonate Genthon 800 mg film-coated tablets when necessary to reach an adequate phosphate level.

If you take more Sevelamer carbonate Genthon 800 mg film-coated tablets than you should

There are no reported overdoses in patients.

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

If you forget to take Sevelamer carbonate Genthon 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.

4. Possible side effects

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

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

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):

Diarrhea • abdominal pain • indigestion • flatulence

In clinical use, cases of itching, rash, slow intestine motility (movement)/blockages in the intestine and perforation in the intestine wall have been reported.

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

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 numbers listed at the end of this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sevelamer carbonate Genthon 800 mg film-coated tablets

Do not store the medical product above 25°C.

Keep the container tightly closed in order to protect from moisture.

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 medicine 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 Genthon 800 mg film-coated tablets contain

The active substance is sevelamer carbonate. Each tablet contains 800 mg of sevelamer carbonate.

What Sevelamer carbonate Genthon 800 mg film-coated tablets look like and contents of the pack

Sevelamer carbonate Genthon 800mg film-coated tablets are oval, white to off-white film-coated tablets.

Each bottle contains 90 tablets.

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

Marketing Authorisation Holder

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