Package leaflet: Information for the user

Sevelamer carbonate Genthon 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Sevelamer carbonate Genthon 800 mg is and what it is used for

Sevelamer carbonate Genthon 800 mg 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 Genthon 800 mg

Do not take Sevelamer carbonate Genthon 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 Genthon 800 mg 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 [Product name]:
- 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) has not been studied. Therefore this medicine is not recommended for use in children below the age of 6 years.

Other medicines and Sevelamer carbonate Genthon 800 mg
Tell your doctor if you are taking, have recently taken or might take any other medicines.

- Sevelamer carbonate Genthon 800 mg 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.

- 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. 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. 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 Genthon 800 mg. Your doctor may monitor the phosphate level in your blood.

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

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

It is unknown whether Sevelamer carbonate Genthon 800 mg 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 Genthon 800 mg treatment.

Driving and using machines
Sevelamer carbonate Genthon 800 mg is unlikely to affect your ability to drive or to use machines.

Sevelamer carbonate Genthon 800 mg contains lactose
Sevelamer carbonate Genthon 800 mg 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 Genthon 800 mg

You must take Sevelamer carbonate Genthon 800 mg 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 for adults and 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 Genthon 800 mg 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 may adjust the dose of Sevelamer carbonate Genthon 800 mg film-coated tablets when necessary to reach an adequate phosphate level.

Follow the diet prescribed by your doctor.

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

If you forget to take Sevelamer carbonate Genthon 800 mg
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 Genthon 800 mg
Taking your Sevelamer carbonate Genthon 800 mg treatment is important to maintain an appropriate phosphate level in your blood. Stopping Sevelamer carbonate Genthon 800 mg would lead to important consequences such as calcification in the blood vessels. If you consider stopping your Sevelamer carbonate Genthon 800 mg 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 Genthon 800 mg:

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:
HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2,
Tel: +353 1 6764971,
Fax: +353 1 6762517,
Website: www.hpra.ie, e-mail: medsafety@hpra.ie.
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

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 Genthon 800 mg contains

- The active substance is sevelamer carbonate. Each Sevelamer carbonate Genthon 800 mg film-coated tablet contains 800 mg of sevelamer carbonate.
- The other ingredients are lactose monohydrate, anhydrous colloidal silica, zinc stearate. The tablet coating contains hypromellose (E464) and diacetylated monoglycerides.

What Sevelamer carbonate Genthon 800 mg looks like and contents of the pack

Sevelamer carbonate Genthon 800 mg 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.

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:
Genthon B.V.
Microweg 22
6545 CM NIJMEGEN
The Netherlands

Manufacturer:
Synthon Hispania S.L.
Castello, 1
Poligono Las Salinas
08830 Sant Boi de Llobregat
Spain

This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark	Sevelamercarbonat Genthon
Belgium	Sevelamer-carbonaat Genthon 800 mg filmomhulde tabletten
Greece	SEVELAMER / DEMO Επικαλυμμένο με λεπτό υμένιο δισκίο 800mg/TAB
Spain	Sevelámero Kern Pharma 800 mg comprimidos recubiertos con película
France	SEVELAMER CARBONATE BIOGARAN 800 mg, comprimés pelliculés
Ireland	Sevelamer carbonate Genthon 800 mg film-coated tablets
Italy	SEVELAMER DOC Generici 800 mg compresse rivestite con film
The Netherlands	Sevelamer carbonaat Genthon 800 mg, filmomhulde tabletten
Portugal	Sevelâmero Genthon, 800 mg, Comprimido revestido por película
United Kingdom	Sevelamer carbonate 800 mg film-coated tablets

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Detailed information on this medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu.