Package leaflet: Information for the user

Lovtelar 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 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 Lovtelar is and what it is used for

Lovtelar 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 Lovtelar

Do not take Lovtelar 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 Lovtelar 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.

Talk to your doctor while taking Lovtelar:
- 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 Lovtelar
Tell your doctor if you are taking, have recently taken or might take any other medicines.

- Lovtelar 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 Lovtelar.

- The effects of medicines such as ciclosporin, mycophenolate mofetil and tacrolimus (medicines used to suppress the immune system) may be reduced by Lovtelar. 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 Lovtelar. 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 Lovtelar. Your doctor may monitor the phosphate level in your blood.

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

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

It is unknown whether Lovtelar 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 Lovtelar treatment.

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

3. How to take Lovtelar

You must take Lovtelar as prescribed by your doctor. They will base the dose on your serum phosphorus level.

The recommended starting dose of Lovtelar tablets 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 Lovtelar 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 Lovtelar when necessary to reach an adequate phosphate level.

Follow the diet prescribed by your doctor.

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

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

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 (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 Website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Lovtelar

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 “EXP”. The expiry date refers to the last day of that month.

This medicine does not require any special temperature 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 Lovtelar contains

- The active substance is sevelamer carbonate. Each Lovtelar film-coated tablet contains 800 mg of sevelamer carbonate.
- The other ingredients are: colloidal anhydrous silica, maize starch pregelatinized 1500 and magnesium stearate.
- The coating contains hypromellose 15cP (E464), HPMC 2910/hypromellose 2910 5cP (E464), acetylated monoglycerides FCC (E472a)
- The blue printing ink contains propylene glycol (E1520), FD&C Blue No.1 (E133), purified shellac (E904).

What Lovtelar looks like and contents of the pack

White to off-white, oval biconvex film-coated tablets, of approximately 21 mm in length marked “C800” on one side.

Lovtelar tablets are available in a cardboard box containing one white opaque HDPE bottle of 180 tablets with PP child resistant cap and a foil induction seal.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Pharmathen S.A.
Dervenakion 6
15351 Pallini, Attiki
Greece

Manufacturer

Pharmathen International S.A.,
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Rodopi Prefecture, Block No 5,
69300 Rodopi,
Greece

and/or

Pharmathen S.A.
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153 51 Pallini Attiki,
Greece

This medicine is authorised in the Member States of the European Economic Area under the following names:

Denmark	Lovtelar
Germany	Lovtelar
Greece	Lovtelar
Spain	Lovtelar 800 mg comprimido recubierto con película
France	Lovtelar
Ireland	Lovtelar 800 mg film-coated tablets
Italy	Lovtelar
Netherlands	Lovtelar 800 mg, filmomhulde tabletten
Sweden	Lovtelar

This leaflet was last revised in <{MM/YYYY}>.