180 film-coated tablets

For oral use.

Tablets must be swallowed whole. Do not chew.
Read the package leaflet before use.

Each tablet contains 800 mg sevelamer carbonate.

Keep out of the sight and reach of children.

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

RenVela
800 mg

film-coated tablets
sevelamer carbonate

United Kingdom/Ireland:
POM

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Medicinal product subject to medical prescription.

EU/1/09/521/003

genzyme
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4FA0053G

Package leaflet: Information for the user

Renvela 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 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 you doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Renvela is and what it is used for

Renvela contains sevelamer carbonate as the active ingredient. It binds phosphate from food in the digestive tract and so reduces serum phosphorus levels in the blood.

Renvela 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.

Renvela 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 Renvela

Do not take Renvela 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 to any of the other ingredients of this medicine (listed in section 6).

Warnings and Precautions
Talk to your doctor before taking Renvela 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.

Children and adolescents
The safety and efficacy in children (below the age of 18 years) has not been studied. Therefore Renvela is 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 Renvela 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 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.
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 Renvela
Tell your doctor if you are taking or have recently taken or might take any other medicines.

- Renvela 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 Renvela.
- The effects of medicines such as ciclosporin, mycophenolate mofetil and tacrolimus (medicines used to suppress the immune system) may be reduced by Renvela. 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 Renvela. Therefore your doctor may monitor the levels of thyroid stimulating hormone in your blood more closely.

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

In some cases where Renvela 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 Renvela intake, or they may consider monitoring the blood levels of that medicine.

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.
It is unknown whether Renvela has any affect on unborn babies.

Tell your doctor if you wish to breast-feed your baby. It is unknown whether Renvela may pass through breast milk and affect your baby.

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

3. How to take Renvela

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

The recommended starting dose of Renvela tablets for adults and older people (> 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 Renvela when necessary to reach an adequate phosphate level.

Patients taking Renvela should adhere to their prescribed diets.

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

If you forget to take Renvela
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.

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

The following side effects have been reported in patients taking Renvela:
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):
diarrhoea, abdominal pain, indigestion, flatulence

Not known (frequency cannot be estimated from the available data):
cases of itching, rash, slow intestine motility (movement)/blockages in the intestine, and perforation in the intestine wall have been reported.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

United Kingdom
You can also report side effects directly via the Yellow Card Scheme at:
www.mhra.gov.uk/yellowcard

Ireland
You can also report side effects directly via IMB Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.imb.ie; e-mail: imbpharmacovigilance@imb.ie

Malta
ADR Reporting, The Medicines Authority, Post-Licensing Directorate, 203 Level 3, Rue D'Argens, GŻR-1368 Gżira
Website: www.medicinesauthority.gov.mt
e-mail: postlicensing.medicinesauthority@gov.mt

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Renvela

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".

Keep the bottle container tightly closed in order to protect from moisture.
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 Renvela contains
- The active substance is sevelamer carbonate. Each Renvela film-coated tablet contains 800 mg of sevelamer carbonate
- The other ingredients are microcrystalline cellulose, sodium chloride and zinc stearate. The tablet coating contains hypromellose (E464) and diacetylated monoglycerides. The printing ink contains iron oxide black (E172), isopropyl alcohol, propylene glycol and hypromellose (E464).

What Renvela looks like and contents of the pack

Renvela film-coated tablets are white tablets with RENVELA 800 imprinted on one side. The tablets are packed in high density polyethylene bottles with a polypropylene cap and an induction seal.
Pack sizes:
1 x 30 tablets per bottle
1 x 180 tablets per bottle
180 tablets (6 bottles of 30 tablets)

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder:
Genzyme Europe B.V.
Gooimeer 10
1411 DD Naarden
The Netherlands

Manufacturer:
Genzyme Ireland Ltd.
IDA Industrial Park
Old Kilmeaden Road
Waterford
Ireland
For any information about this medicine, please contact the local representative of the Marketing Authorisation holder.

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Other sources of information
Detailed information on this medicine is available on the European Medicines Agency web site:
http://www.ema.europa.eu.
This leaflet is available in all EU/EEA languages on the European Medicines Agency website.