Package leaflet: Information for the user

Renagel 800 mg film-coated tablets
sevelamer hydrochloride

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 your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Renagel is and what it is used for

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

Renagel is used to control the levels of phosphate in the blood of adult kidney failure patients on haemodialysis or peritoneal dialysis treatment.

Adult patients whose kidneys have failed and who are undergoing haemodialysis or peritoneal dialysis are not able to control the level of serum phosphate in their blood. The amount of phosphate then rises (your doctor will call this hyperphosphataemia). 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.

Renagel may be used with other medicines which include calcium or vitamin D supplements to control the development of renal bone disease.

2. What you need to know before you take Renagel

Do not take Renagel:
- if you have low levels of phosphate in your blood (your doctor will check this for you).
- if you have bowel obstruction.

- if you are allergic to sevelamer or to any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor before taking Renagel if any of the following applies to you:
- if you are not on dialysis
- if you have swallowing problems
- if you have problems with motility (movement) in your stomach and bowel
- if you have symptoms of delayed emptying of stomach contents such as feeling of fullness, nausea and/or vomiting
- if you have prolonged diarrhoea or pain in the abdomen (symptoms of active inflammatory bowel disease)
- if you have undergone major surgery on your stomach or bowel.

Talk to your doctor while taking Renagel:
- 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 a low or high level of calcium in your blood. Since Renagel 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.

Changing treatment:
When you switch from another phosphate binder to Renagel, your doctor might consider monitoring the levels of bicarbonate in your blood more closely because Renagel may decrease the levels of bicarbonate.

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.

Children and adolescents
The safety and efficacy in children (below the age of 18 years) has not been studied. Therefore Renagel is not recommended for use in this population.

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

- Renagel 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 Renagel.

- The effects of medicines such as ciclosporin, mycophenolate mofetil and tacrolimus (medicines used in transplant patients) may be reduced by Renagel. Your doctor will advise you if you are taking these medicines.

- In certain people taking levothyroxine (a thyroid hormone) and Renagel, increased levels of thyroid stimulating hormone (TSH, a substance in your blood which helps control your body's chemical functions) may very rarely be observed. Therefore your doctor may monitor the levels of TSH in your blood more closely.

- If you are taking medicine such as omeprazole, pantoprazole, or lansoprazole to treat heartburn, gastroesophageal reflux disease (GERD), or gastric ulcers, you should consult your doctor when taking Renagel.

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

In some cases where Renagel 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 Renagel intake, or he/she may consider monitoring the blood levels of that medicine.

Pregnancy and breast-feeding
The safety of Renagel has not been established in pregnant or breast-feeding women. Renagel should only be given to pregnant or breast-feeding women if clearly needed.

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.

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

3. How to take Renagel

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. He will base the dose on your serum phosphate level. The recommended starting dose of Renagel for adults and the elderly (>65 years) is one or two tablets with each meal 3 times a day.

Initially your doctor will check the levels of phosphate in your blood every 2-3 weeks and may adjust the dose of Renagel when necessary (between 1 and 5 tablets of 800 mg per meal) to reach an adequate phosphate level.

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

Patients taking Renagel should adhere to their prescribed diet and liquid intake.

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

If you forget to take Renagel
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 a preceding symptom in very rare cases of blockages in your intestine, it is important to inform your doctor or pharmacist of this symptom before or during the use of Renagel.

The following side effects have been reported in patients taking Renagel:
Very common (may affect more than 1 in 10 people):
nausea, vomiting.
Common (may affect up to 1 in 10 people):
diarrhoea, indigestion, abdominal pain, constipation, flatulence.
Uncommon (may affect up to 1 in 100 people):
increased acidity of the blood.
Very rare (may affect up to 1 in 10000 people):
hypersensitivity.
Not known (frequency cannot be estimated from the available data):
cases of itching, rash, abdominal pain, slow intestine motility (movement), inflammation of abnormal small pouches (called diverticula) in the large intestine, blockages in the intestine (signs include: severe bloating; abdominal pain, swelling or cramps; severe constipation), rupture in the intestine wall (signs include: severe stomach pain, chills, fever, nausea, vomiting, or a tender abdomen), 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.

5. How to store Renagel

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the carton and bottle after "EXP". The expiry date refers to the last day of that month.

Do not store this medicine above 25 °C. Keep the bottle tightly closed in order to protect from moisture.

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 to protect the environment.

6. Contents of the pack and other information

What Renagel contains

- The active substance is sevelamer hydrochloride. Each tablet contains 800 mg sevelamer hydrochloride.
- The other ingredients are silica colloidal anhydrous and stearic acid, hypromellose (E464), diacetylated monoglycerides, iron oxide black (E172) and propylene glycol.

What Renagel looks like and contents of the pack

Renagel tablets are film coated, off white, oval tablets with Renagel 800 imprinted on one side. The tablets are packed in high density polyethylene bottles with a child resistant polypropylene closure and an induction seal.

Pack sizes are:
1 bottle of 100 tablets
1 bottle of 180 tablets
multipacks containing 180 tablets (6 bottles of 30 tablets)
multipacks containing 360 tablets (2 bottles of 180 tablets)
multipacks containing 540 tablets (3 bottles of 180 tablets)

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Genzyme Europe B.V.
Paasheuvelweg 25
1105 BP Amsterdam
The Netherlands

Manufacturer:
Genzyme Ireland Limited
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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