PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

This medicine is dispensed with a doctor's prescription only

Renvela 2.4 g Powder

Active ingredient - Each sachet of powder contains:
Sevelamer carbonate anhydrous 2.4 g
Inactive ingredients: see section 6.

Read this leaflet carefully in its entirety before using this medicine. This leaflet contains concise information about the medicine. Keep this leaflet; you may need it later.
If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed to treat your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.
This medicine is not intended for children and adolescents under 18 years of age.

1. WHAT IS THIS MEDICINE INTENDED FOR?

The medicine is indicated to:
- balance high phosphate blood levels in adult patients with kidney failure receiving dialysis (hemodialysis or peritoneal dialysis).
- balance high phosphate blood levels in adult patients with chronic kidney disease not on dialysis, with blood phosphate levels of 1.78 mmol and above.

This medicine should be used with other treatments such as calcium supplements and vitamin D to prevent the development of bone disease.

Therapeutic group: phosphate binders.
Sevelamer carbonate binds phosphate from food within the digestive system and thus reduces serum phosphorus levels in the blood.

2. BEFORE USING THE MEDICINE

Do not use this medicine if:
- You have a known sensitivity to the active ingredient sevelamer, or to any of the ingredients of the medicine (see section 6)
- You have low blood phosphate levels (your doctor will check this for you)
- You have bowel obstruction

Special warnings regarding use of the medicine:
Before treatment with Renvela, inform the doctor if you are suffering from any of the effects listed below:
- swallowing difficulties
- problems with motility in the stomach and bowel
- frequent vomiting
- active inflammation of the bowel
- if you have undergone major surgery on the stomach or bowel

Talk to your doctor if while taking Renvela:
- you experience severe abdominal pain, intestinal or stomach disorders, or blood in the stool (gastrointestinal bleeding). These symptoms can be due to serious inflammatory bowel disease caused by sevelamer crystals in your bowel. Contact your doctor who will decide whether or not to continue treatment.

Additional treatments
Due to your kidney condition or your dialysis treatment, you may:
- develop abnormal levels (low or high) of calcium in your blood. Since Renvela does not contain calcium, the doctor may prescribe a calcium supplement for you.
- have a low amount of vitamin D in your blood. Your doctor may monitor the levels of vitamin D in your blood and prescribe a vitamin D supplement, as necessary. If you do not take multivitamin supplements, you may also have low levels of vitamins A, E, K and folic acid and therefore, your doctor may also check the levels of these vitamins in the blood test and tell you to take vitamin supplements, if necessary.
- have a disturbed level of bicarbonate in your blood and increased acidity in the blood and other body tissues. Your doctor should monitor the level of bicarbonate in your blood.

Special instructions for patients on peritoneal dialysis
You may develop peritoneal dialysis-related peritonitis (infection of the abdominal fluids). This risk can be reduced by observing strict sterile conditions when changing the bags. Inform the doctor immediately if you experience any new sign or symptom of abdominal discomfort, 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 resulting from low levels of vitamins A, D, E, K and folic acid.

Children and adolescents:
Renvela is not intended for use in children and adolescents under 18 years of age.

Drug interactions:
If you are taking, or have recently taken, other medicines, including nonprescription medicines and nutritional supplements, inform the doctor or pharmacist. Especially:
- Do not take Renvela with ciprofloxacin (an antibiotic).
- If you are taking medicines to treat heart rhythm problems or to treat epilepsy, consult your doctor when taking Renvela.
- The medicine Renvela may reduce the activity of medicines such as: ciclosporin, mycophenolate mofetil and tacrolimus (medicines used to suppress the immune system). Consult the doctor if you are taking these medicines.
- Thyroid hormone deficiency is uncommonly observed in certain people taking levothyroxine (used to treat low thyroid hormone levels) and Renvela. Therefore the doctor may check thyroid hormone levels in your blood more frequently.
- If you are taking proton pump inhibitors to treat heartburn, gastroesophageal reflux or a stomach ulcer, such as omeprazole, pantoprazole or lansoprazole, consult your doctor when taking Renvela. He may monitor your blood phosphate levels, since these medicines may reduce the effectiveness of Renvela.

Your attending doctor will regularly check for drug interactions between Renvela and other medicines.

In some cases it is necessary to take Renvela at the same time as another medicine. It is possible that the doctor may recommend that you take the other medicine one hour before or 3 hours after taking Renvela. The doctor may also consider checking your blood levels of the other medicine.

Use of the medicine and food:
Take the medicine with a meal.

Pregnancy and breastfeeding:
Pregnancy
Consult your doctor before taking this medicine if you are pregnant, think you may be pregnant or are planning to become pregnant. The potential risk of Renvela during human pregnancy is unknown. Talk to your doctor who will decide if you can continue the treatment with Renvela.
Breastfeeding
Before taking Renvela, consult your doctor if you are breastfeeding or are planning to breastfeed. It is not known if Renvela passes into breast milk and if it may harm your baby. Talk to your doctor who will decide if you can breastfeed your baby or not, and if it is necessary to stop Renvela treatment.

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

Important information about some of the ingredients of the medicine:
This medicine contains less than 1 millimole (23 mg) of sodium in 2.4 g powder, in other words the preparation is essentially "sodium-free". This medicine contains 25.27 mg propylene glycol in every 2.4 gram powder.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Consult with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.
The dosage and treatment regimen will be determined by the doctor only. Your dosage will be determined based on the levels of phosphorus in your blood.
Mix each Renvela sachet in 60 ml of water. Drink the suspension within 30 minutes of preparation. It is important to drink all of the liquid and then rinse the glass with more water and drink this as well to ensure that all of the powder is swallowed.
The usual recommended starting dose for Renvela is 2.4-4.8 g per day, divided equally over three meals. The exact starting dose and regimen will be determined by the doctor.

Do not exceed the recommended dose.

Tests and follow-up:
Initially, your doctor will check the levels of phosphate in your blood every 2-4 weeks and will adjust the dose of Renvela to reach an adequate phosphate level.
While taking Renvela it is very important to adhere strictly to the recommended diet.

If you accidentally took a higher dosage
If you took an overdose, or if a child has accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine
If you forgot to take this medicine at the designated time, do not take a double dose. Take the next dose at the usual time with a meal and consult the doctor. Never take two doses together to compensate for a forgotten dose.
Adhere to the treatment regimen prescribed by the doctor.

If you stop taking Renvela
Renvela treatment is important for maintaining appropriate phosphate levels in your blood. Stopping Renvela treatment will lead to significant consequences, such as calcification of the blood vessels. If you consider stopping Renvela treatment, first refer to a doctor or pharmacist.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Renvela may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Refer to a doctor as soon as possible if you are suffering from constipation. Constipation is a very common side effect (may occur in more than 1 user in 10). Constipation may be an early symptom of a blockage in your intestine.

Some side effects could be serious. If you have any of the following side effects, seek immediate medical attention:
- Allergic reaction (signs include: rash, hives, swelling, trouble breathing). This is a very rare side effect (may occur in up to 1 user in 10,000).
- Blockage in the intestine (signs include: severe bloating, abdominal pain, swelling or cramps, severe constipation) has been reported. Frequency is not known (frequency has not been determined).
- 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 (frequency has not been determined).
- Serious inflammation of the large bowel (signs include: severe abdominal pain, stomach or intestinal disorders, or blood in the stool [gastrointestinal bleeding]) and crystal residues in the intestine have been reported. Frequency is not known (frequency has not been determined).

Additional side effects reported in patients who took Renvela:
Very common side effects - effects that occur in more than one in ten users:
vomiting, upper abdominal pain, nausea.
Common side effects - effects that occur in 1-10 in 100 users:
diarrhea, abdominal pain, indigestion, flatulence.
Side effects of unknown frequency (effects whose frequency has not yet been determined):
itching, rash, slowed intestinal motility.

If a side effect occurs, if one of the side effects worsens, or if you are suffering from a side effect not mentioned in this leaflet, consult the doctor.

Reporting side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il/

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning.
Do not induce vomiting unless explicitly instructed to do so by the doctor.
Do not use the medicine after the expiry date (exp. date) that appears on the carton and sachet. The expiry date refers to the last day of that month.
Drink the suspension within 30 minutes of preparation.
Storage: do not store above 30°C.
Do not throw away medicines into the household waste or wastewater. Ask your pharmacist how to throw away medicines you no longer need. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, each Renvela 2.4 g powder sachet also contains:
Natural & artificial citrus cream, propylene glycol alginate, sodium chloride powder, sucralose, ferric oxide (yellow).
What the medicine looks like and the contents of the package: Sealed sachets containing pale yellow powder. The sachets are packaged in a carton.
There are 60 or 90 sachets per carton. Not all package sizes may be marketed.

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, please ask your doctor.

License Holder and Importer and its address: sanofi-aventis Israel ltd., 10 Beni Gaon Street, Netanya.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
145-75-33193

The leaflet was revised in January 2021.