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

This medicine is dispensed with a doctor's prescription only

Renvela 800 mg Tablets

sanofi

Active ingredient:
Each film-coated tablet contains:
Sevelamer carbonate anhydrous 800 mg
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 the 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 in the digestive tract and thereby reduces serum phosphorus levels in the blood.

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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 (the 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 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

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folic acid and therefore, your doctor may also check the levels of these vitamins in a blood test and tell you to take vitamin supplements, as 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 stiffness, constipation, fever, chills, nausea or vomiting.
Expect tighter monitoring of problems arising from low vitamin A, D, E, K and folic acid levels.

Use in children and adolescents:
Renvela is not intended for 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.

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- 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.

The doctor treating you will regularly check drug interactions between Renvela and other medicines.
In some cases, Renvela has to be taken at the same time as another medicine. The doctor may recommend that you take the other medicine one hour before or three hours after taking Renvela. The doctor may also consider checking the 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

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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 mmol sodium (23 mg) in 800 mg, i.e., it is essentially 'sodium-free'.

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.

The usual recommended starting dose: 1 to 2 tablets of 800 mg with each meal, 3 times a day.
Do not exceed the recommended dose.
Swallow the tablets whole.
Do not crush/halve/chew the tablet. The tablet is film-coated.
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.
When taking Renvela, it is very important to strictly follow 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.

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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. Do not take two doses together to compensate for a forgotten dose. Adhere to the treatment regimen as recommended by the doctor.

If you stop taking Renvela
Renvela treatment is important for maintaining appropriate phosphate levels in your blood. Stopping Renvela treatment will have 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).

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- 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 10 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): cases of itching, rash, slow 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 the 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

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do so by the doctor.
Do not use the medicine after the expiry date (exp. date) that appears on the bottle. The expiry date refers to the last day of that month.

Storage conditions:
Do not store above 30°C. Keep the bottle closed tightly to protect from moisture.
Shelf-life after first opening: 30 days.
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 800 mg tablet also contains:
Microcrystalline cellulose, purified water, sodium chloride, zinc stearate, hypromellose, diacetylated monoglycerides.

What the medicine looks like and the contents of the package:
White, film-coated tablets with "RV800" engraved on one side.
The tablets are packaged in bottles of 30 or 180 tablets per bottle.
Not all package sizes are 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.

Registration holder and importer and its address:
Sanofi Israel Ltd. Greenwork Park P.O. box 47 Yakum

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 145-74-33197

Revised in June 2024 according to MOH guidelines.