

RENVELA® FILM-COATED TABLETS

Sevelamer Carbonate 800mg

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What Renvela is used for

Renvela is used for patients who have kidneys that do not work properly are not able to control the level of serum phosphorus 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.

How Renvela works

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.

Before you use Renvela

When you must not use it

Do not take Renvela if:

- You are allergic (hypersensitive) to sevelamer carbonate, sevelamer hydrochloride, or to any of the other ingredients of this medicine (listed in Section 8 below).
- Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- You have bowel obstruction.

Before you start to use it

Check with your doctor before taking Renvela if:

- You have swallowing problems
- You have problems related with motility (movement) in your stomach and bowel
- You are being sick frequently
- You have active inflammation of the bowel
- You have undergone major surgery on your stomach or bowel
- You have severe constipation.

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.

Taking other medicines

Please tell your doctor or pharmacist if you are taking, 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.

How to use Renvela

Always take Renvela exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Swallow your tablets orally in whole with plenty of water.
- Do not crush, chew or break into pieces.
- You must take Renvela with meals.

How much to use

Your doctor will prescribe Renvela to you based on your serum phosphorus level.

The recommended starting dose of Renvela tablets for adults and the elderly (> 65 years) is **one to two tablets of 800mg with each meal, 3 times a day.**

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.

Renvela is not recommended for use in children and adolescents below 18 years of age.

When to use it

Take Renvela at about the same time each day unless your doctor tells you otherwise.

How long to use it

Continue taking your medicine for as long as your doctor tells you.

If you forget to use it

- If you forget to take your tablet, leave out that dose completely and take the next tablet at the usual time.

- Do not take a double dose to make up for a forgotten tablet.
- If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you use too much (overdose)

There are no reported overdoses in patients. In the event of a possible overdose you should contact your doctor immediately. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

Things you must do

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine if:

- You are pregnant, think you may be pregnant or are planning to have a baby. It is unknown whether Renvela has any effect on unborn babies.
- You wish to breast-feed your baby. It is unknown whether Renvela may pass through breast milk and affect your baby.

Things you must not do

- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.
- Do not stop taking Renvela, or change the dosage, without checking with your doctor.

Things to be careful of

Gastrointestinal Adverse Events

Cases of dysphagia and esophageal tablet retention have been reported in association with use of the tablet formulation of sevelamer, some requiring hospitalization and intervention. Consider using sevelamer suspension in patients with a history of swallowing disorders.

Cases of bowel obstruction, bleeding gastrointestinal ulcers, colitis, ulceration, necrosis, and perforation have also been reported with sevelamer use.

Inflammatory disorders may resolve upon Renvela discontinuation.

Treatment with Renvela should be re-evaluated in patients who develop

severe gastrointestinal symptoms.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.gov.my [Consumers Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Renvela

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

Storage

- Keep this medicine out of sight and reach of children.
- Do not use Renvela after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.
- Keep the bottle container tightly closed in order to protect from moisture. This medicinal product does not require any special storage conditions.
- Store at 30°C (86°F): excursions permitted to 25-40°C (77-104°F).

Disposal

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like

Renvela tablets, for oral use are white to off-white oval tablets engraved with “RV800” on one side.

The tablets are packed in high density polyethylene bottles with a polypropylene cap and an induction seal. Pack size:

- 1 x 30 tablets per bottle
- 1 x 180 tablets per bottle
- 1 x 270 tablets per bottle.

Not all pack sizes may be marketed.

Ingredients:

- The active substance is sevelamer carbonate. Each Renvela film-

coated tablet contains 800 mg of sevelamer carbonate.

- The inactive ingredients are microcrystalline cellulose, hypromellose, diacetylated monoglycerides, sodium chloride and zinc stearate

MAL Numbers:

Renvela 800mg film-coated tablet
MAL20102007AZ

Manufacturer and Product Registration Holder

Manufacturer

Sanofi Winthrop Industrie
Carbon Blanc, France

Product Registration Holder

Sanofi-aventis (Malaysia) Sdn. Bhd.
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Date of revision

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