

Renvela[®]

Sevelamer carbonate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Renvela.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Renvela against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet. You may need to read it again.

What Renvela is used for

Renvela contains the active substance sevelamer carbonate and is used to treat hyperphosphatemia, a condition caused by too much dietary phosphorus being retained in your body due to a diseased kidney.

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.

Renvela helps to remove excess phosphorus that has built up in your body by binding the phosphorus that is in the food that you eat.

Your doctor, however, may have prescribed Renvela for another purpose.

Ask your doctor if you have any questions about why it has been prescribed for you.

This medicine is only available with a doctor's prescription.

Before you take Renvela

When you must not take Renvela

Do not take Renvela if you have an allergy to:

- any medicine containing sevelamer carbonate (the active ingredient)
- any of the ingredients listed at the end of this leaflet
- any other similar medicine, such as sevelamer hydrochloride.

Symptoms that may indicate an allergic reaction include

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Tell your doctor if you are experiencing these symptoms.

Do not take Renvela if you have:

- hypophosphatemia, a condition where you do not have enough phosphorus in your body
- a bowel obstruction.

Renvela should not be used after the expiry date (exp) printed on the pack. If you take this medicine after the expiry date it may have no effect at all, or worse, an unexpected effect.

Renvela should not be used if the packaging is torn or shows signs of tampering.

Do not give Renvela to children.

The safety and efficacy of Renvela in children under the age of 18 years as not been established.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor or pharmacist if you have:

- allergies to any other medicines or substances such as foods, preservatives or dyes.
- swallowing problems
- severe constipation
- problems with movement in your stomach and bowel
- active inflammation of the bowel
- undergone major surgery on your stomach or bowel
- you have or have had any other medical conditions, including a bowel obstruction or hypophosphatemia

- thyroid problems.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby.

Tell your doctor about any of the above before you take Renvela.

Renvela powder contains sucralose.

Additional Information

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.
- 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 tenderness, constipation, fever, chills, nausea or vomiting.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines (including vaccinations), medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may be affected by Renvela or may affect how well Renvela works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

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.

Renvela should not be taken at the same time as ciprofloxacin (an antibiotic).

Thyroid hormone deficiency may uncommonly be observed in certain people taking levothyroxine (used to treat low thyroid hormone levels) and Renvela. Therefore your doctor may monitor the levels of thyroid stimulating hormone in your blood more closely.

If you are taking medicines for heart rhythm problems, stomach problems, or for epilepsy, you should consult your doctor before taking Renvela.

How to take Renvela

How much to take

The recommended starting dose of Renvela is 2.4 g to 4.8 g per day to be divided over 3 meals.

For tablets, this means one to two 800 mg tablets with each meal three times a day. For powder this means up to one full sachet (1.6 g) with each meal, three times a day.

The dose will depend on your serum phosphorus level.

Follow all directions given to you by your doctor or pharmacist carefully.

These directions may differ from the information contained in this leaflet.

How to take it

Tablets

Swallow Renvela tablets whole with a glass of water. Do not crush, chew or break into pieces.

If you are having difficulty swallowing Renvela tablets, speak to your doctor. You may be prescribed Renvela powder as an alternative.

Powder

The 1.6 g powder for oral suspension should be dispersed in 40 ml of water per sachet.

The 2.4 g powder for oral suspension should be dispersed in 60 ml of water per sachet.

The powder isn't expected to fully dissolve in water. When dispersed it creates a cloudy white suspension in which small particles are visible.

Drink within 30 minutes of being prepared. It is important to drink all of the dose and it may be necessary to rinse the glass with water and drink this as well to ensure that all of the powder is swallowed.

How long to take it

Renvela helps lower your dietary phosphate. It does not cure your condition. Therefore, you must continue to take it as directed by your doctor.

You may have to take phosphate-lowering medicines for the rest of your life. If you stop taking Renvela, your phosphate levels may rise again. It is important to keep taking your medicines even if you feel well.

Do not stop taking Renvela. Your doctor may need to change the dose of your other medicines if you stop taking Renvela, so you should only stop when your treating doctor tells you to.

If you forget to take it

If you miss a dose, do not take an extra dose to make up for the one you missed. Take the next dose at the usual time with your meal.

It is important to take Renvela as prescribed by your doctor.

If you take too much (overdose)

Immediately telephone your treating doctor or Poisons Information Centre telephone 0800 POISON or 0800 764 766, or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Renvela. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep telephone numbers of these places handy.

While you are taking Renvela

Things you must do

If you become pregnant while you are taking Renvela, tell your doctor.

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Renvela.

Be sure to keep all your doctor's appointments so your progress can be checked.

Your doctor will check your progress and monitor your phosphorus levels from time to time. This helps to ensure you are getting the right dose of Renvela.

Things you must not do

Do not give Renvela to anyone else, even if they have the same condition as you.

Do not use Renvela to treat any other complaints unless your doctor tells you to.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Side Effects

Tell your doctor, pharmacist or nurse as soon as possible if you do not feel well while you are taking Renvela.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- allergic reaction
- vomiting
- nausea
- constipation
- diarrhoea
- flatulence
- indigestion
- abdominal pain
- pain in hand and/or foot
- fatigue
- loss of appetite
- muscle spasms
- headache
- urinary tract infection
- cough.

Tell your doctor immediately if you notice any of the following symptoms:

- rash, itching or hives on the skin
- severe constipation
- dizziness.

If any of the following happen, tell your doctor immediately or go to the Accident and Emergency at your nearest hospital:

- shortness of breath

- wheezing or difficulty in breathing
- swelling of the face, lips, tongue or other parts of the body
- 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 crystal deposit in your bowel.

Other side effects not listed above may occur in some patients. Tell your doctor if you notice anything making you feel unwell when you are taking, or soon after you have finished taking Renvela.

After using Renvela

Storage

Keep Renvela in a cool dry place where the temperature stays below 25°C. Do not put Renvela in the refrigerator. Do not put it in the bathroom or near the sink. Do not leave it in the car or on window sills. Heat and dampness can destroy some medicines.

Keep Renvela where young children cannot reach it. A locked cupboard at least one and a half meters above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Renvela or your Renvela tablets or powder have passed their expiry date, ask your pharmacist what to do with any tablet or powder that is left over.

Product description

What Renvela looks like

Renvela is available as tablets or powder.

Renvela tablets are white oval film-coated tablets imprinted with

'REVELA 800' on one side and are blank on the other side.

Renvela powder is pale yellow in colour.

Ingredients

Tablet

Active ingredients:

Sevelamer carbonate

Other ingredients:

- Acetylated monoglycerides
- Hypromellose E-15
- Hypromellose E-5
- Isopropyl alcohol
- Microcrystalline cellulose
- Opacode
- Propylene glycol
- Sodium chloride
- Zinc stearate.

Powder

Active ingredients:

Sevelamer carbonate

Other ingredients:

- 'Natural and Artificial Citrus Cream' proprietary flavouring
- Iron oxide yellow
- Propylene glycol alginate
- Sodium chloride
- Sucralose.

Supplied by

Renvela is supplied in New Zealand by:

sanofi-aventis new zealand ltd
56 Cawley St
Ellerslie, Auckland,
New Zealand

Toll Free Number (medical information): 0800 283 684

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