AIP539026A

Package leaflet: Information for the user

Renvela® 0.8 g powder for oral suspension

sevelamer carbonate

Is this leaflet hard to see or read? Phone 0800 035 2525 for help.

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 of the side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Renvela is and what it is used for

Renvela contains sevelamer carbonate as the active substance. It binds phosphate from food in the digestive tract and so reduces serum phosphorus levels in the blood.

This medicine is used to control hyperphosphataemia (high blood phosphate levels) in:
- adult patients on dialysis (a blood clearance technique). It can be used in patients undergoing haemodialysis (using a blood filtration machine) or peritoneal dialysis (where fluid is pumped into the abdomen and an internal body membrane filters the blood);
- adult patients with chronic (long-term) kidney disease who are not on dialysis and have a serum (blood) phosphorus level equal to or above 1.78 mmol/L.
- paediatric patients with chronic (long-term) kidney disease above the age of 6 and above a certain height and weight (used to calculate body surface area by your physician).

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

2. What you need to know before you take Renvela

Do not take Renvela if:
- you are allergic to the active substance or to any of the other ingredients of this medicine (listed in section 6).
- you have low levels of phosphate in your blood (your doctor will check this for you)
- you have bowel obstruction

Warnings and precautions
Talk to you doctor before taking Renvela if any of the following applies to you:
- problems with motility (movement) in your stomach and bowel
- being sick frequently
- active inflammation of the bowel
- have undergone major surgery on your stomach or bowel

Talk to your doctor while taking Renvela:
- 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 low or high levels of calcium in your blood. Since this medicine 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.
- have disturbed level of bicarbonate in your blood and increased acidity in the blood and other body tissue. Your doctor should monitor the level of bicarbonate in your blood.

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.

Children
The safety and efficacy in children (below the age of 6 years) have not been studied. Therefore, this medicine is not recommended for use in children below the age of 6 years.

Other medicines and Renvela
Tell your doctor if you are taking or 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 treat low thyroid hormone levels) and Renvela. Therefore, your doctor may monitor the levels of thyroid stimulating hormone in your blood more closely.
- Medicines treating heartburn and reflux from your stomach or oesophagus, such as omeprazole, pantoprazole, or lansoprazole, known as "proton pump inhibitors", may reduce the efficacy of Renvela. Your doctor may monitor the phosphate level in your blood

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

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. Your doctor may also consider monitoring the levels of that medicine in your blood.

Pregnancy and breast-feeding
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. 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.

It is unknown whether Renvela is excreted in breast milk and may affect 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 using machines
Renvela is unlikely to affect your ability to drive or to use machines.

Excipients
This medicine contains less than 1 mmol sodium (23 mg) per sachet, that is to say essentially 'sodium-free'.
This medicine contains 8.42 mg propylene glycol in each 0.8g sachet.

3. How to take Renvela

You must take Renvela as prescribed by your doctor. They will base the dose on your serum phosphorus level.

For a 0.8 g dose, the powder for oral suspension should be dispersed in 30 ml of water per sachet. Drink within 30 minutes of being prepared. It is important to drink all of the liquid 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. Instead of water, the powder may be pre-mixed with a small amount of cold beverage (about 120 ml or half a glass) or food (about 100 g) and consumed within 30 minutes.
Do not heat Renvela powder (e.g. microwave) or add to hot foods or liquids.

The recommended starting dose of this medicine for adults and elderly is 2.4-4.8g per day equally divided over three meals. Check with your doctor, pharmacist or nurse if you are not sure. The exact starting dose and regimen will be determined by your doctor.

Take Renvela after your meal or with food.

For 0.4 g doses, the powder in the sachet may be divided. In this case the 0.4 g dose of Renvela powder must be measured using the dosing spoon provided in the carton.

Always use the dosing spoon provided in the carton.

Use in children and adolescents
The recommended starting dose of Renvela for children is based on their height and weight (used to calculate body surface area by your physician). For children, the powder is preferred, as tablets are not appropriate in this population. This medicine should not be given on an empty stomach and should be taken with meals or snacks. The exact starting dose and regimen will be determined by your doctor.
For doses of less than 0.8 g, the powder in the sachet may be divided. The 0.4 g dose of Renvela powder must be measured using the dosing spoon provided in the carton.

Preparation using a dosing spoon

Use the provided dosing spoon for each 0.4 g dose of Renvela powder.

For a 0.4 g dose:
- Shake the sachet holding the top corner before opening, to move the powder to the bottom of the sachet
- Open the sachet by tearing along the marked line.
- Ensure the dosing spoon is dry.
- Hold the dosing spoon horizontally and pour the powder out of the sachet into the dosing spoon.
- Fill the powder to the spoon level.
- Do not tap the dosing spoon to compact the powder.
- Mix the powder from the dosing spoon in 30 ml of water. Stir the suspension and drink it within 30 minutes of being prepared. It is important to drink all of the liquid to ensure that all of the powder is swallowed.
- Close the sachet by folding over twice.
- The remaining powder may be used within 24 hours for the next dose.
- Discard sachets of powder that have been opened for more than 24 hours.

Initially, your doctor will check the levels of phosphorus in your blood every 2-4 weeks and may adjust the dose of Renvela when necessary to reach an adequate phosphate level.

Follow the diet prescribed by your doctor.

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

If you forget to take Renvela
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.

If you stop taking Renvela
Taking your Renvela treatment is important to maintain an appropriate phosphate level in your blood. Stopping Renvela would lead to important consequences such as calcification in the blood vessels. If you consider stopping your Renvela treatment, contact your doctor or pharmacist first.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Constipation is a very common side effect (may affect more than 1 in 10 people). It can be an early symptom of a blockage in your intestine. In case of constipation, please inform your doctor or pharmacist.

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Some side effects could be serious. If you get any of the following side effects, seek immediate medical attention:
- Allergic reaction (signs including rash, hives, swelling, trouble breathing). This is a very rare side effect (may affect up to 1 in 10,000 people).
- Blockage in the intestine (signs include: severe bloating; abdominal pain, swelling or cramps; severe constipation) has been reported. Frequency is not known (frequency cannot be estimated from the available data).
- 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
- 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. Frequency is not known.

Other side effects have been reported in patients taking Renvela:

Very common (may affect more than 1 in 10 people):
vomiting, upper abdominal pain, nausea

Common (may affect up to 1 in 10 people):
diarrhoea, stomach ache, indigestion, flatulence

Not known (frequency cannot be estimated from available data):
cases of itching, rash, slow intestine motility (movement)

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Renvela

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

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

The reconstituted suspension must be administered within 30 minutes of reconstitution. This medicine does not require any special storage conditions. Discard the sachet after 24 hours of opening.

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 protect the environment.

6. Contents of the pack and other information

What Renvela contains
- The active substance is sevelamer carbonate. Each sachet contains 0.8 g of sevelamer carbonate.
- The other ingredients are propylene glycol alginate (E405), citrus cream flavour, sodium chloride, sucralose and iron oxide yellow (E172).

What Renvela looks like and contents of the pack
Renvela powder for oral suspension is a pale yellow powder supplied in a foil sachet with a heat seal. The sachets are packaged in an outer carton.
A 0.4 g dosing spoon is provided in the carton.

Pack size: 90 sachets per carton

Marketing Authorisation Holder and Manufacturer

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

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