Approved Patient Information Leaflet for RENVELA TABLETS

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

RENVELA® TABLETS 800 mg film coated tablets

Sevelamer carbonate

Sugar free.

Read all of this leaflet carefully before taking RENVELA TABLETS:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- RENVELA TABLETS has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What RENVELA TABLETS is and what it is used for

RENVELA TABLETS binds phosphate from food in the digestive tract, thereby reducing serum phosphorus levels in the blood.

RENVELA TABLETS 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 (stomach area) 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 above 1,78 mmol/L.

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 (bone breaks).

2. What you need to know before you take RENVELA TABLETS

Do not take RENVELA TABLETS if:

- you are allergic to sevelamer or to any of the components of RENVELA TABLETS (listed in section 6)
- you have low levels of phosphate in your blood (your doctor will check this for you)
- you have a bowel obstruction.

Warnings and precautions

Take special care with RENVELA TABLETS:

If any of the following applies to you, please consult your doctor before taking RENVELA TABLETS:

- swallowing problems
- problems with motility (movement) in your stomach and bowel
- being sick (vomiting) frequently
- active inflammation of your bowel
- you have undergone major stomach or bowel surgery.

Children

The safety and efficacy in children (below the age of 18 years) have not been established. RENVELA TABLETS is therefore not recommended in children.

Contact your doctor immediately if you experience any new signs or symptoms of abdominal (stomach) distress, such as (see section 4):

- swelling in your stomach area or rigidity
- abdominal (stomach) pain or tenderness
- chills and fever
- nausea and vomiting (feeling sick or being sick)
- severe constipation.

Talk to your doctor while taking RENVELA TABLETS:

- if you experience severe abdominal (stomach) pain, stomach or intestinal disorders, or blood in your stools (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 on continuing the treatment or not.

Your doctor or health care provider may need to re-evaluate treatment options.

Due to either your kidney condition or your dialysis treatment, you may 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 if necessary. If you do not take multivitamin supplements, you may develop low levels of vitamins A, D, E, K and folic acid in your blood as a result of your kidney disease or treatment with RENVELA TABLETS. Your doctor will monitor the blood levels of these vitamins and prescribe supplemental vitamins if necessary.

Special note for patients on peritoneal dialysis

You may develop peritonitis (infection of your abdominal (stomach) 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.

Other medicines and RENVELA TABLETS:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

RENVELA TABLETS should not be taken at the same time as ciprofloxacin (an antibiotic, used to treat certain bacterial infections).

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

The effects of medicines such as ciclosporin, mycophenolate mofetil and tacrolimus (medicines used to suppress the immune system) may be reduced by RENVELA TABLETS. Your doctor will advise you if you are taking these medicines.

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

If you are taking medicine to treat heartburn, gastro-oesophageal reflux disease (GERD) or gastric ulcers, such as omeprazole, pantoprazole or lansoprazole, known as proton pump inhibitors, you should consult your doctor when taking RENVELA TABLETS. Cases of increased phosphate levels have been reported when taken together. Your doctor may monitor the phosphate level in your blood.

Your doctor may check for interactions between RENVELA TABLETS and other medicines on a regular basis.

Your doctor may advise you to take specific medicines 1 hour before or 3 hours after you have taken RENVELA TABLETS, or your doctor may consider monitoring the levels of that medicine in your blood (see section 3).

RENVELA TABLETS with food and drink:

You must take RENVELA TABLETS with meals.

Pregnancy and breastfeeding:

The safety of RENVELA TABLETS has not been established in pregnant or breastfeeding women. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking RENVELA TABLETS. It is unknown whether RENVELA TABLETS 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 TABLETS treatment.

Driving and using machines:

RENVELA TABLETS is not expected to affect your ability to drive a vehicle or operate machinery. Take care until you know how RENVELA TABLETS affects you.

Excipients:

RENVELA TABLETS contains less than 1 mmol sodium (23 mg) per tablet that is to say essentially "sodium-free".

3. How to take RENVELA TABLETS

Do not share medicines prescribed for you with any other person.
Always take RENVELA TABLETS exactly as your doctor has told you. Check with your doctor if you are not sure. Your doctor will base the dose on your serum phosphorus level.
The 800 mg tablets can be taken three times a day with meals at the dose decided by your doctor.
The tablets should be swallowed whole and should not be crushed, chewed or broken into pieces prior to administration.

In some cases where RENVELA TABLETS 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 TABLETS intake, or they may consider monitoring the blood levels of that medicine (see section 2).

Your doctor will check the levels of phosphorus in your blood periodically and they may adjust the dose of RENVELA TABLETS when necessary to reach an adequate phosphate level.

Follow the diet prescribed by your doctor.

Your doctor will tell you how long your treatment with RENVELA TABLETS will last. If you have the impression that the effect of RENVELA TABLETS is too strong or too weak, tell your doctor or pharmacist.

If you take more RENVELA TABLETS than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Always take the labelled medicine package with you, whether there are any RENVELA TABLETS left or not.

If you forget to take RENVELA TABLETS:

If you have missed one dose, this dose should be skipped, 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.

4. Possible side effects

RENVELA TABLETS can have side effects.

Not all side effects reported for RENVELA TABLETS are included in this leaflet. Should your general health worsen or you experience any untoward effects while taking RENVELA TABLETS, please consult your health care provider for advice.

If any of the following happens, stop taking RENVELA TABLETS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all serious side effects. If you have them, you may have had a serious reaction to RENVELA TABLETS.

You may need urgent medical attention or hospitalisation.

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

- severe pain in your stomach area with blood in your stools or vomit, which may be signs of a perforation in your intestinal wall
- constipation, which may be an early sign of a blockage in your intestine (see section 2)
- serious inflammation of the large bowel (symptoms include: severe stomach pain, stomach or intestinal disorders, or blood in your stools [gastrointestinal bleeding]).

Tell your doctor as soon as possible if you notice any of the following side effects that have been reported:

Frequently occuring side effects:

- vomiting, upper stomach pain, nausea
- diarrhoea, pain in your stomach area, indigestion, flatulence.

Side effects occurred with a frequency unknown:

- itching, rash, slow intestine motility (movement)/blockages in the intestine and perforation in the intestine (see section 2).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get any side effects, talk to your doctor, pharmacist or nurse.

This includes any possible side effects not listed in this leaflet.

You can report any side effects directly to Sanofi's Pharmacovigilance Unit at za.drugsafety@sanofi.com (email) or 011 256 3700 (tel).

You can also report side effects to SAHPRA via the "**Adverse Drug Reaction Reporting Form**" found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

5. How to store RENVELA TABLETS

Store at or below 25 °C. Protect from moisture.

Keep tablets in the bottle until required for use.

Keep bottle tightly closed.

STORE ALL MEDICINE OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What RENVELA TABLETS contains:

The active substance is sevelamer carbonate.

Other ingredients are microcrystalline cellulose, sodium chloride, zinc stearate, Opadry Clear (diacetylated monoglycerides, hypromellose) and Opacode Black ink (hypromellose, black iron oxide).

What RENVELA TABLETS looks like and contents of the pack:

White to off-white oval tablet, printed with "RENVELA 800" on crown, single side, in black ink.

RENVELA TABLETS are packaged in white, high-density polyethylene (HDPE) bottles, with a white, child-resistant polypropylene cap and a foil induction seal. The bottle for the 30 tablets pack size is packaged in an outer carton.

Pack sizes: 30, 180, 270.

Holder of Certificate of Registration:

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