PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

RENVELA® TABLETS (film coated tablets)

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 RENVELA TABLETS CONTAINS:

Active ingredient: Each film coated tablet contains 800 mg of sevelamer carbonate on an anhydrous basis.

Inactive ingredients: Microcrystalline cellulose, sodium chloride, zinc stearate, Opadry clear (diacetylated monoglycerides, hypromellose) and Opacode black ink (hypromellose, iron oxide black). Sugar free.

WHAT RENVELA TABLETS IS USED FOR:

RENVELA TABLETS binds phosphate from food in the digestive tract and so reduces serum phosphorus levels in the blood.

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).

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 (see WHAT RENVELA TABLETS CONTAINS)
- You have low levels of phosphate in your blood (your doctor will check this for you)
- You have a bowel obstruction.

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 frequently
- Active inflammation of the bowel
- Have undergone major surgery on your stomach or bowel.

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 distress, such as (see POSSIBLE SIDE EFFECTS):

- Abdominal swelling or rigidity
- Abdominal pain or tenderness

- Chills and fever
- Nausea and vomiting (feeling sick or being sick)
- Severe constipation.

Your doctor or healthcare professional may need to re-evaluate treatment options.

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 these blood levels and prescribe supplemental vitamins if necessary.

Taking 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, please consult your doctor, pharmacist or other healthcare professional before taking RENVELA TABLETS.

Driving and using machinery:

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

Taking other medicines with RENVELA TABLETS:

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

RENVELA TABLETS 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 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 uncommonly 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, gastroesophageal reflux disease (GERD) or gastric ulcers, such as omeprazole, prantoprazole, or lansoprazole, you should consult your doctor when taking RENVELA TABLETS. Cases of increased phosphate levels have been reported when taken together.

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

HOW TO TAKE RENVELA TABLETS:

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

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The 800 mg tablets can be taken three times a day with meals at the dosage 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 Taking other medicines with RENVELA TABLETS).

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.

If you take more RENVELA TABLETS than you should:

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

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.

POSSIBLE SIDE EFFECTS:

RENVELA TABLETS may 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 doctor, pharmacist or other healthcare professional 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. You may have had a serious an allergic reaction to RENVELA TABLETS, which require urgent medical attention.

Tell your doctor or health care professional as soon as possible if you experience the following:

- Severe abdominal pain with blood in the stools or vomit, which may be signs of a perforation in the intestine wall
- Constipation, which may be an early sign of a blockage in your intestine (see Take special care with RENVELA TABLETS).

Tell your doctor if you notice any of the following side effects that have been reported frequently in patients taking RENVELA TABLETS:

- Vomiting, constipation, upper abdominal pain, nausea.
- Diarrhoea, abdominal pain, indigestion, flatulence

The following side effects have been reported:

Frequency unknown: itching, rash, slow intestine motility (movement)/blockages in the intestine and perforation in the intestine (see Take special care with RENVELA TABLETS).

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

STORAGE AND DISPOSAL OF RENVELA TABLETS:

Store at or below 25 °C.

Protect from moisture. Keep tablets in the bottle until required for use.

Keep the bottle tightly closed.

STORE ALL MEDICINE OUT OF REACH OF CHILDREN.

PRESENTATION OF RENVELA TABLETS:

RENVELA TABLETS are packaged in white high-density polyethylene bottles (HDPE), 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.

IDENTIFICATION OF RENVELA TABLETS:

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

REGISTRATION NUMBER:

RENVELA TABLETS: 45/32.16/0305

NAME AND ADDRESS OF REGISTRATION HOLDER:

sanofi-aventis south africa (pty) ltd

2 Bond Street,

Midrand,

1685

Signed: _____

DATE OF PUBLICATION:

Date of registration: 05 June 2014

Date revised: 09 September 2019

Signed: _____