Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Sevelamer Taro 800 mg **Tablets**	**Sevelamer Taro 2.4 g** **Powder for oral suspension**
Active ingredient: Each film-coated tablet contains: sevelamer carbonate anhydrous 800 mg	**Active ingredient:** Each sachet of powder contains: sevelamer carbonate anhydrous 2.4 gram

Inactive ingredients and allergens: See the section 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. Keep the leaflet. You may need to read it again.
If you have any further questions, consult your doctor or pharmacist.
This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is this medicine intended for?

This medicine is intended for:

- Controlling high levels of phosphate in blood of adult patients who are on dialysis (hemodialysis or peritoneal dialysis).
- Controlling high levels of phosphate in blood of adult patients with a chronic kidney disease who are not on dialysis, have a blood phosphorus level equal to or above 1.78 mmol/l.

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

Therapeutic group: phosphate binders.

Sevelamer carbonate binds phosphate from food in the digestive tract and in this way reduces serum phosphorus levels in the blood.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient sevelamer or to any of the other ingredients in this medicine (see section 6).
- You have low blood phosphate levels (the doctor will check this for you).
- You have a blockage in your bowel.

Special warnings about using this medicine
Before using Sevelamer Taro, tell your doctor if you have:

- difficulty swallowing
- trouble with stomach and bowel motility
- frequent vomiting
- an active inflammation in your bowel
- had extensive stomach or intestinal surgery

Talk to your doctor while taking this medicine if:
you experience severe abdominal pain, intestine or stomach disorders or blood in the stool (gastrointestinal bleeding).
These symptoms can be due to a severe inflammatory disease in your bowel caused by sevelamer crystals in your bowel. Contact your doctor who will decide whether to continue the treatment or not.

Other treatments
Your kidney's condition or your dialysis treatments may cause you to:

- develop abnormal (low or high) levels of calcium in your blood. Sevelamer Taro does not contain calcium so your doctor may prescribe you with a calcium supplement.
- have low levels of vitamin D in your blood. Your doctor may check your vitamin D levels and prescribe you with a vitamin D supplement if necessary. If you are not taking a multi-vitamin supplement you may also have low levels of vitamins A, E, K, and folic acid. Your doctor may, therefore, order a blood test to check your level of these vitamins, and tell you to take a vitamin supplement if necessary.
- have disturbed levels 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 instructions for patients on peritoneal dialysis
You may develop peritoneal dialysis-related peritonitis (infection of the abdominal fluids). This risk can be reduced by observing strict sterile conditions while changing the bags. Inform the doctor immediately if you experience any new sign or symptom of abdominal discomfort, abdominal swelling, abdominal pain, abdominal tenderness or abdominal stiffness, constipation, fever, chills, nausea or vomiting.
Expect tighter monitoring for problems related to low levels of vitamin A, D, E, K, and folic acid.

Use in children and adolescents
This medicine is not intended for children and adolescents under 18 years old.

Tests and follow-up
Initially, your doctor will check the levels of phosphate in your blood every 2-4 weeks and will adjust the dose of Sevelamer Taro so that you reach a normal phosphate level.

Other medicines and Sevelamer Taro
If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

- Do not take Sevelamer Taro with ciprofloxacin (an antibiotic).

- If you are taking medicines to treat heart rhythm problems or to treat epilepsy, consult your doctor when taking Sevelamer Taro.
- Sevelamer Taro may reduce the activity of medicines such as: cyclosporine, mycophenolate mofetil, and tacrolimus (medicines used to suppress the immune system). Consult the doctor if you are taking these medicines.
- Thyroid hormone deficiency is occasionally observed in certain people who have taken levothyroxine (a medicine used to treat low levels of thyroid hormone) and Sevelamer Taro. Your doctor may check thyroid hormone levels in your blood more frequently.
- If you are taking proton-pump inhibitors to treat heartburn, gastroesophageal reflux or a stomach ulcer, such as omeprazole, pantoprazole or lansoprazole, consult your doctor when you take Sevelamer Taro. Your doctor may monitor your blood phosphate levels because these medicines may reduce the effect of Sevelamer Taro.

Your doctor will regularly check for interactions between Sevelamer Taro and other medicines. In certain cases, you will have to take Sevelamer Taro at the same time as the other medicine. Your doctor may advise you to take the other medicine one hour before or three hours after taking Sevelamer Taro. Your doctor may also consider checking the levels of the other medicine in your blood.

Using this medicine and food
Take this medicine with a meal.

Pregnancy and breastfeeding
Pregnancy
Consult your doctor before you start taking this medicine if you are pregnant, think you may be pregnant or are planning to get pregnant. The potential risk using of Sevelamer Taro during pregnancy is unknown. Talk to your doctor who will decide if you can continue the treatment with Sevelamer Taro.
Breastfeeding
Consult your doctor before taking Sevelamer Taro if you are breastfeeding or are planning to breastfeed. It is not known whether Sevelamer Taro passes into breast milk and whether it may harm your baby. Talk to your doctor who will decide if you can breastfeed your baby or not, and whether it is necessary to stop Sevelamer Taro treatment.

Driving and using machines
This medicine is unlikely to affect your ability to drive or use machines.

Important information about some of this medicine's ingredients
Sevelamer Taro 800 mg tablets contain lactose. If a doctor has told you that you have an intolerance to certain sugars tell your doctor before using this medicine.
Sevelamer Taro 2.4 g powder contains less than 1 millimole (23 mg) of sodium in 2.4 g, which means that this medicine is considered "sodium-free".

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Only your doctor will determine your dose and how you should take this medicine. Your dose will be determined based on the levels of phosphate in your blood.

Sevelamer Taro 800 mg tablets: Swallow the tablet whole. Do not crush, split, or chew the tablet before taking it.
The recommended starting dosage is usually: 1 to 2 800 mg tablets with every meal, 3 times a day.

Sevelamer Taro 2.4 g powder: Disperse each 2.4 g sachet of Sevelamer Taro in 60 ml of water. Drink the suspension within 30 minutes of being prepared. It is important to drink all of the liquid and then rinse the glass with additional water and drink this as well to ensure that all of the powder is swallowed.
The recommended starting dose is usually 2.4-4.8 g a day equally divided over three meals. Your doctor will decide what your exact starting dose is and how you should take the medicine.

Do not exceed the recommended dose.

When taking Sevelamer Taro, it is very important to strictly follow the recommended diet.

If you have accidentally taken a higher dose
If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine
If you forget to take this medicine at the scheduled time, do not take a double dose. Take the next dose at the usual time with your meal and consult your doctor. Do not take two doses together to make up for a forgotten dose.
Adhere to the treatment as recommended by your doctor.

If you stop taking this medicine
The treatment with Sevelamer Taro is important to maintaining normal phosphate levels in your blood. Stopping Sevelamer Taro would lead to significant consequences such as calcification in the blood vessels. If you consider stopping your treatment, contact your doctor or pharmacist first.

Do not take medicines in the dark! Check the label and dose every time you take the medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or the pharmacist.

4. Side effects

Like all medicines, taking Sevelamer Taro may cause side effects in some people. Do not be alarmed by this list of side effects; you may not experience any of them.
Consult your doctor as soon as possible if you are constipated. Constipation is a very common side effect (may affect more than 1 in 10 users). Constipation can be an early symptom of a blockage in your bowel.

Some side effects could be serious. If you get any of the following side effects, seek immediate medical attention:

- Allergic reaction (signs include: rash, hives, swelling, trouble breathing). This is a very rare side effect (may affect up to 1 in 10,000 users).
- Blockage in the intestine (signs include: severe bloating; abdominal pain, swelling or cramps, severe constipation). Frequency is not known.
- Rupture in the intestinal wall (signs include: severe abdominal pain, chills, fever, nausea, vomiting, or a tender abdomen). Frequency is not known.
- Severe inflammation in the large intestine (signs include: severe abdominal pain, stomach or intestine disorder, or blood in the stool (gastrointestinal bleeding) and crystal deposits in the intestine). Frequency is not known.

Additional side effects reported in patients who took this medicine:

Very common side effects (affect more than one in ten users):
vomiting, upper abdominal pain, nausea.

Common side effects (affect 1-10 in 100 users)
diarrhea, abdominal pain, indigestion, flatulence.

Side effects of unknown frequency (frequency has not been determined yet):
cases of itch, rash, slowed intestinal motility.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects
You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:
https://sideeffects.health.gov.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Do not store above 25°C
- Sevelamer Taro 800 mg tablets: Keep the bottle tightly closed to protect from moisture.
- Sevelamer Taro 2.4 g powder: Drink the suspension within 30 minutes of being prepared.
- Do not throw away any medicine in the wastewater or domestic waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient each Sevelamer Taro 800 mg tablet also contains:
Lactose monohydrate, hypromellose, diacetylated monoglycerides, zinc stearate, silica, colloidal anhydrous.

In addition to the active ingredient each Sevelamer Taro 2.4 mg Powder sachet also contains:
Microcrystalline cellulose, carmellose sodium, sucralose, lemon flavor, orange flavor, iron oxide yellow.

What the medicine looks like and contents of the pack:
Sevelamer Taro 800 mg tablets –
Oval, white to off-white film-coated tablets imprinted with SVL on one side.
The tablets are packaged in bottles of 180 tablets.

Sevelamer Taro 2.4 g powder –
Off-white to yellow powder packed in sachets.
Sachets are packaged in cartons of 60 per carton.

Registration holder's name and address: Taro International Ltd., 14 Hakitor St., Haifa Bay 2624761

Manufacturer's name and address:
Synthon Hispania S.L., Castello 1, Poligono Las Salinas ,08830 Sant Boi De Llobregat, Barcelona, Spain

Revised in November 2021 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
Sevelamer Taro 800 mg tablets: 157.83.34686
Sevelamer Taro 2.4 g powder: 164.79.35536