The format of this leaflet has been defined by the MOH and its content has been checked and approved by it in 1.2015. The leaflet was updated according to the MoH guidelines in 9.2018.

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) 1986
This medicine is to be supplied by physician's prescription only

Read the entire leaflet carefully before you start taking this medicine.

Fosrenol 750 mg; 1000 mg oral powder

Each sachet contains **750 mg; 1000 mg of the active ingredient lanthanum (as lanthanum carbonate hydrate)** accordingly.

Inactive ingredients- see section 6 (Additional information) in this leaflet.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains essential information about this medicine. If you have any further questions, refer to the physician or the 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.

The medicine is not intended for children under the age of 18. The safety and efficacy of Fosrenol in children below the age of 18 years has not been established.

Fosrenol should be taken with or immediately after food.

If you need to have an x-ray, please inform your physician that you are taking Fosrenol as it may affect the results.

1. What is this medicine intended for?

Fosrenol is indicated as a phosphate binding agent for use in the control of hyperphosphataemia in chronic renal failure patients on haemodialysis or continuous ambulatory peritoneal dialysis (CAPD). Fosrenol is also indicated in patients with chronic kidney disease not on dialysis with high serum phosphate levels (>1.78 mmol/L) in whom a low phosphate diet alone is insufficient to control serum phosphate levels.

Therapeutic activity:
Fosrenol is a medicine which reduces the body's absorption of phosphate from food by binding with it in your digestive tract. Phosphate which has bonded to Fosrenol cannot be absorbed through the intestinal wall.

Therapeutic group: drugs for the treatment of hyperphosphatemia.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient lanthanum carbonate hydrate or to any of the other ingredients that this medicine contains.
- If you have too little phosphate in your blood (hypophosphataemia).

Special warnings regarding the use of this medicine

• Before using this medicine, tell your physician if:

You suffer, or have suffered in the past from:

- stomach or intestinal cancer
- inflammatory bowel disease including ulcerative colitis or Crohn's disease
- abdominal surgery, or infection or inflammation of the abdomen/bowel (peritonitis)
- Stomach or intestinal ulcers
- blockage of the intestine or slow motility (movement) in the intestine (e.g. constipation and stomach complications due to diabetes)
- Reduced liver or kidney function

Tests to perform before using this medicine
If you have reduced kidney function your physician may decide to check the level of calcium in your blood from time to time. If you have too little calcium, you may then be given extra calcium.

If you need to have an x-ray, please inform your physician that you are taking Fosrenol as it may affect the results.

Other medicines and Fosrenol
If you are taking, have recently taken, or might take other medicines, including nonprescription medications and food supplements, inform your physician or pharmacist.

Fosrenol can affect how certain medicines are absorbed from your digestive tract. If you are taking one of the following medicines, they should be taken at least 2 hours before or after taking Fosrenol:

- Chloroquine- for rheumatism and malaria
- Ketoconazole – for fungal infections
- Tetracycline or doxycycline antibiotics

It is not recommended that you take oral floxacin antibiotics (including ciprofloxacin) within 2 hours before or 4 hours after taking Fosrenol.

- Levothyroxine – for an underactive thyroid – it should be taken 2 hours before or after taking Fosrenol. Your physician may want to monitor the levels of thyroid-stimulating hormone (TSH) in your blood more closely.

Using the medicine and food

Fosrenol should be taken with or immediately after food. See Section 3 for instructions on how to take Fosrenol.

Pregnancy and breastfeeding

Fosrenol should not be taken during pregnancy.
If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your physician or pharmacist for advice before taking this medicine.
As it is not known whether the medicine can be transferred to a child in breast-milk, you should not breast-feed whilst taking Fosrenol. If you are breast-feeding, ask your doctor or pharmacist for advice before taking any medicines.

Driving and using machines

This medicine may sometimes lead to a feeling of vertigo or dizziness. If you experience these side effects it may affect your ability to drive or operate machinery.

3. How should you use the medicine?

- Always use according to the physician's instructions. You should check with the physician or the pharmacist if you are unsure.

You should take Fosrenol with or immediately after food.
Side effects such as nausea and vomiting are more likely if you take Fosrenol before your meal.

Fosrenol oral powder is intended to be mixed with soft food (e.g. applesauce or other similar soft food product) and then swallowed. Additional fluid is not necessary.

Do not open the sachet until ready to use. Mix all of the contents of the sachet into 1-2 spoonfuls of soft food (e.g. applesauce or other similar soft food product), taking care to see that the entire dose is mixed with the food. Ensure that the entire oral powder/food mixture is eaten immediately (within 15 minutes).
Never store any oral powder /food mixture for use at a later time.

- The dosage and treatment will be determined only by the physician.

Your physician will tell you how many sachets of oral powder you must take with each meal (your daily dose will be divided between meals).
The number of sachets that you take will depend on the amount of phosphate in the food you eat and your blood phosphate level.
Before starting on Fosrenol oral powder, your doctor may have used Fosrenol chewable tablets that are available in a number of strengths to find the correct dose for you.
The recommended dose of oral powder is usually sachet of 750 or 1000 mg, three times a day with meals.
Fosrenol works by binding phosphate from the food in your gut. It is very important to take Fosrenol at every meal. If you change your diet, contact your physician as you may need to take extra Fosrenol. Your physician will tell you what to do in this case.
Do not exceed the recommended dose.

Test and follow up

Before starting to use the medicine the physician will refer you to check the level of phosphate in your blood. During treatment (every 2-3 weeks) your physician will check the level of phosphate in your blood and may increase your dose until the level of phosphate in your blood is acceptable and regularly thereafter.

If you have accidently taken a higher dose

If you take too much Fosrenol contact your physician to assess the risk and obtain advice. Symptoms of overdose may be nausea and headaches.
If you have taken an overdose, or if a child has accidentally swallowed the medicine, go immediately to a hospital emergency room and bring the medicine package with you.

If you forgot to take Fosrenol

It is important to take Fosrenol with every meal. If you forget to take the medicine at the scheduled time, do not take a double dose to make up for the forgotten dose. Take the next dose at the usual time, with your next meal and consult your physician.

If you stop taking the medicine

Persist with the treatment as recommended by the physician. Even if there is an improvement in your health, do not stop treatment with this medicine without consulting the physician.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take the medicine. Wear glasses if you need them.

If you have any other questions regarding the use of the medicine, consult the physician or the pharmacist.

4. <u>Side effects</u>

As with any medicine, Fosrenol may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

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

- Rupture in the intestinal wall (signs include: severe stomach pain, chills, fever, nausea, vomiting, or a tender abdomen). This is a rare side effect (may affect up to 1 in 1,000 people).
- Blockage in the intestine (signs include: severe bloating; abdominal pain, swelling or cramps; severe constipation). This is an uncommon side effect (may affect up to 1 in 100 people).
- Contact your doctor if you have new or severe constipation, it could be an early sign of blockage in your intestine. Constipation is a common side effect (may affect 1 in 10 people).

Other less serious side effects include the following:

Very Common side effects (may affect more than 1 user in 10):
• Nausea, vomiting, diarrhoea, stomach pain, headache, itching, rash

Common side effects (may affect up to 1 to 10 users in 100):
• Heartburn, flatulence
• Hypocalcaemia (too little calcium in your blood) is also a common side effect; the symptoms of which can include tingling in the hands and feet, muscle and abdominal cramps or spasms of the facial and feet muscles.

Uncommon side effects (may affect up to 1 to 10 users in 1000):
• Tiredness; feeling of discomfort; chest pain, weakness; swollen hands and feet; body pain; dizziness; vertigo; belching
inflammation of the stomach and intestines (gastroenteritis); indigestion; irritable bowel syndrome; dry mouth; tooth disorders;
inflammation of the gullet or mouth; loose stools; increases in certain liver enzymes, parathyroid hormone;
aluminum, calcium and glucose in the blood; increased or reduced phosphate level in the blood; thirst; weight decrease;
joint pain; muscle pain; weakness and thinning of the bones (osteoporosis); lack of and increased appetite; inflammation of the larynx; loss of hair; increased sweating; taste disturbance and increased white blood cell count.

If any side effect gets worse, or if you suffer from a side effect not mentioned in the leaflet, you should consult the physician.

Side effects can be reported to the Ministry of Health by clicking on the link "Adverse Drug Reactions Repot" that appears on the home page of the Ministry of Health web site (www.health.gov.il), which leads to an online form for reporting side effects. Alternatively you can use the following link:

/https://sideeffects.health.gov.il

5. How to store the medicine

Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction form the physician.
Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

Store at a temperature below 30° C.

Medicines should not be disposed of 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. Additional information

In addition to the active ingredient the medicine also contains:
Dextrates (hydrated), colloidal anhydrous silica, magnesium stearate

Fosrenol contains Glucose If you have been told by your physician that you have an intolerance to some sugars, contact your physician before taking this medicinal product.
Each sachet of Fosrenol 750 mg and 1000 mg contains 641.7 and 855.6 mg accordingly of Dextrates, containing glucose.

What does the medicine look like and what are the contents of the package?

Fosrenol powder is presented as a white to off-white oral powder in a sachet.
The sachets are supplied in a carton of 90 sachets. (Outer carton contains 9 cartons of 10 sachets).

Registration holder and his address: Takeda Israel Ltd.,25 Efal st.,Petach Tikva 4951125

Manufacturer name and address:
Shire Pharmaceuticals Ireland Limited,
Blocks 2 & 3 Miesian Plaza, 50-58 Baggot Street Lower, Dublin 2, Ireland

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
750 mg – 153-35-34025-00
1000 mg – 153-36-34022-00