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

This medicine is dispensed with physician's prescription only

Fosrenol 750 mg oral powder	**Fosrenol 1000 mg oral powder**
Each sachet contains 750 mg	Each sachet contains 1000 mg

of the active ingredient lanthanum (as carbonate hydrate)

Inactive ingredients and allergens: See section 2 "Important information about some of this medicine's ingredients" and section 6 ("Additional information") in this leaflet.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your physician 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.
This medicine is not intended for users under the age of 18. The safety and efficacy of Fosrenol in children below the age of 18 years has not been examined.

It is important to take the medicine with or immediately after food.

Inform your physician if you need to undergo X-ray imaging, as use of Fosrenol may affect the results.

1. What is this medicine intended for?

The medicine is indicated for reduction of high blood phosphate levels (hyperphosphataemia) in chronic renal failure patients on haemodialysis or ambulatory peritoneal dialysis. The medicine is also indicated for patients with chronic kidney disease not on dialysis with high serum phosphate levels (greater than 1.78 mmol/L), which are not controlled by low phosphate diet alone.

Therapeutic activity: Fosrenol binds phosphate originating from food in the intestine. Phosphate bound in such manner cannot be absorbed in the body; thus, Fosrenol assists in reduction of blood phosphate level.

Therapeutic group: medicines for treatment of hyperkalaemia and 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 in this medicine (listed in section 6).
- If you have low phosphate levels in your blood (hypophosphataemia).

Special warnings about using this medicine

Before treatment with Fosrenol, tell your doctor 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, infection or inflammation of the abdomen/intestines (peritonitis)
- Stomach or intestinal ulcers
- Intestinal obstruction or slow intestinal motility (e.g. constipation and stomach complications due to diabetes)
- Reduced liver or kidney function

Tests and follow up

Before you start using the medicine, your physician will refer you for a blood phosphate level test.
During the treatment period, every 2-3 weeks, your physician will check the level of phosphate in your blood and may increase your dosage until the level of phosphate in your blood is acceptable.

If you have reduced kidney function, your physician may decide to check your blood calcium level from time to time. If you have too little calcium, you may receive a calcium supplement.

Inform your physician if you need to undergo X-ray imaging, as use of Fosrenol may affect the results.

If you are required to undergo gastrointestinal endoscopy, inform your physician that you are taking Fosrenol, since the person performing endoscopy may notice residues of Fosrenol (lanthanum) in the gastrointestinal system.

Drug interactions

If you are taking, have recently taken or may take other medicines, including non-prescription medications and dietary supplements, tell your doctor or pharmacist.

Fosrenol may affect the absorption of certain medicines from the digestive tract.

- If you are taking one of the following medicines, they should be taken at least 2 hours before or 2 hours after taking Fosrenol:
  - chloroquine - for gout (rheumatism) and malaria.
  - ketoconazole - for fungal infections.
  - tetracycline or doxycycline antibiotics.
  - levothyroxine (for underactive thyroid) - it should be taken 2 hours before or after taking Fosrenol. Your physician may want to closely monitor the levels of TSH (thyroid-stimulating hormone) in your blood.
- oral floxacin antibiotics (including ciprofloxacin) – wait 2 hours before or 4 hours after taking Fosrenol.

Using this medicine and food

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

Pregnancy and breastfeeding

Do not use the medicine during pregnancy.
If you are pregnant or breastfeeding, think you may be pregnant, or are planning to have a baby, ask your physician or pharmacist for advice before using this medicine.
As it is not known whether the medicine is transferred to a baby in breast milk, you should not breastfeed while using Fosrenol.
If you are breastfeeding, ask your doctor or pharmacist for advice before taking any medicines.

Driving and using machines
This medicine may sometimes cause dizziness or a feeling of vertigo. If you experience these sensations, you should be careful while driving or operating machinery.

Important information about some of this medicine's ingredients
Fosrenol contains glucose. If you have been told by your physician that you have an intolerance to certain sugars, consult your physician before using this medicine.
Each sachet of Fosrenol 750 mg and 1000 mg contains 641.7 and 855.6 mg of dextrates containing glucose, respectively.

3. How to use this medicine?

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

You should take Fosrenol with or immediately after food.
Side effects such as nausea and vomiting are more likely if you take the medicine before the meal.
Fosrenol oral powder is intended to be mixed with soft food (e.g. applesauce or other similar 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 full spoons of soft food, making sure that the entire dose is mixed with the food. Ensure that the entire mixture of oral powder and food is eaten immediately (within 15 minutes).
Do not store any Fosrenol powder mixed with food for use at a later time.

The dosage and treatment regimen will be determined only by your physician.
Your physician will tell you how many sachets 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 you start using Fosrenol powder, your physician may have told you to use Fosrenol chewable tablets to find the suitable dosage for you. Fosrenol chewable tablets are available in a number of strengths, enabling small dosage increments.
The recommended dosage is usually a sachet of 750 or 1000 mg, 3 times a day with meals.

Fosrenol works by binding phosphate from the food in the gut. Therefore, it is very important to take Fosrenol with every meal. If you change your diet, contact your physician, as you may need to take an additional dose of Fosrenol. Your physician will tell you what to do in this case.

Do not exceed the recommended dose.

If you have accidently taken a higher dose
If you have accidently taken a higher dose, contact your physician to assess the risk and obtain advice. Symptoms of overdose may be manifested as nausea and headaches.
If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a physician or go to a hospital emergency room and bring the medicine package with you.

If you forget to take Fosrenol
It is important to take Fosrenol with every meal. If you forget to take Fosrenol 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 this medicine
Adhere to the treatment as recommended by your physician. Even if your health improves, do not stop taking this medicine without consulting your physician.

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

4. Side effects
Like with all medicines, using Fosrenol may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Some side effects may be serious. If you experience any of the following side effects, seek immediate medical attention:
- Rupture in the intestinal wall (signs include severe abdominal pain, chills, fever, nausea, vomiting or abdominal tenderness). This is a rare side effect (may affect up to 1 in 1000 users).
- Intestinal obstruction (signs include severe bloating; abdominal pain, swelling or cramps; severe constipation). This is an uncommon side effect (may affect up to 1 in 100 users).
- Contact your physician if you have new or severe constipation, since it could be an early sign of intestinal obstruction. Constipation is a common side effect (may affect 1 in 10 users).

Other less serious side effects include the following:
Very common side effects (may affect more than 1 in 10 users):
- Nausea, vomiting, diarrhoea, abdominal pain, headache, itching, rash.

Common side effects (may affect up to 1 in 10 users)
- Heartburn, flatulence (gas in the bowel)
- Low blood calcium levels (hypocalcaemia) is also a common side effect; the symptoms may include tingling sensation in the hands and feet, muscle and abdominal cramps or spasms of the facial and leg muscles.

Uncommon side effects (may affect up to 1 in 100 users):
- 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 levels of certain liver enzymes, parathyroid hormone; increases in levels of 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 appetite or increased appetite; inflammation of the larynx; loss of hair; increased sweating; taste disturbance and increased white blood cell count.

Unknown frequency (the frequency of these effects has not been established yet):

- Medicine residues in the gastrointestinal system

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 physician.

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: Store below 30°C

Do not throw away any medicine via wastewater or household waste. Ask the 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, this medicine also contains:
dextrates (hydrated), colloidal anhydrous silica and magnesium stearate.

What the medicine looks like and contents of the pack:
Fosrenol powder is a white to off-white oral powder packed in a sachet.
A box contains 90 sachets (9 small carton packs of 10 sachets each).

Registration holder's name and address: Takeda Israel Ltd., 25 Efal St., Petach Tikva 4951125

Manufacturer's name and address:
Takeda Pharmaceuticals International AG Ireland Branch, Dublin, Ireland

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

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