

The format of this leaflet has been defined by the Ministry of Health and its content has been checked and approved by it in 10.2012. The leaflet was updated according to the MoH guidelines in 10.2018.

**Patient leaflet in accordance with the
Pharmacists' Regulations (preparations), 1986**

The dispensing of this medicine requires a
physician's prescription.

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

FOSRENOL 500 MG, 750 MG, 1000 MG Chewable tablets

Each chewable tablet contains **500 mg; 750 mg;
1000 mg of the active ingredient Lanthanum (as lanthanum carbonate hydrate)
respectively.**

For Inactive ingredients, see section 6: "Additional information" in this leaflet.

Read this leaflet carefully and in its entirety before using this medicine.

This leaflet contains summarized information regarding the medicine. If you have additional questions please refer to your physician or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their ailment is similar.

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

Attention: Do not swallow! **It is imperative to chew the tablet completely.**

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

Inform your physician if you are about to have an X-ray examination, since the use of Fosrenol may affect the results.

1. What is this medicine intended for?

Fosrenol is indicated for reducing phosphate level in the blood, in chronic renal failure patients on dialysis.

Fosrenol is also indicated in patients with chronic kidney disease not on dialysis with high serum phosphate levels, in whom a low phosphate diet alone is insufficient to control serum phosphate levels.

Therapeutic activity: Fosrenol is bound in the intestine with dietary phosphorus. This binding prevents its absorption by the body, and thus Fosrenol helps in lowering the phosphate level in the blood.

Therapeutic group: Drugs for treatment of hyperkalaemia and hyperphosphataemia.

2. Before using the medicine:

Do not use the medicine if:

- if you are sensitive (allergic) to the active ingredient lanthanum carbonate hydrate or to any of the other ingredients of this medicine (listed in section 6).
- if you suffer from hypophosphataemia (low levels of phosphates in the blood).

Special warnings regarding the use of the medicine:

Before using Fosrenol, 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

It is very important to chew completely Fosrenol tablets and not to swallow them whole or incompletely chewed. This will reduce the risk of adverse gastrointestinal complications like rupture in the intestine wall, blockage in the intestine, constipation (see section 4).

Test to perform before using this medicine

If you have reduced kidney function your doctor 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 doctor that you are taking Fosrenol as it may affect the results.

Other medicines and Fosrenol

If you are taking, or have taken recently, or might take any other medicines including non-prescription medicines and nutritional supplements, inform the physician or pharmacist.

Fosrenol can affect how certain drugs are absorbed from your digestive tract. If you are taking any of the following medicines, you should take them at least two hours before or after taking Fosrenol:

- chloroquine – for the treatment of rheumatism or malaria.
- ketoconazole – for the treatment of fungal infections
- antibiotics such as tetracycline or doxycycline

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 under active thyroid – it should be taken 2 hours before or 2 hours 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 breast-feeding:

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 doctor or pharmacist for advice before taking this medicine.

As it is not known whether the drug 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, be careful while driving or operating machinery.

3. How to use the medicine?

Always use according to the physician's instructions. Check with the physician or pharmacist if you are not sure.

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. The tablets must be chewed completely and not swallowed whole. To aid with chewing, the tablets may be crushed. Additional fluid is not necessary.

The dosage and manner of treatment will be decided by the physician only.

Your physician will tell you how many tablets you must take with each meal (your daily dose will be divided between meals). The number of tablets that you take will depend on the amount of phosphate in the food you eat and your blood phosphate levels.

The usual acceptable dose is 3 tablets a day, divided between the different 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.

Tests and follow up

Every 2-3 weeks your doctor will check the level of phosphate in your blood and may increase your dose until the level of phosphate in your blood is acceptable.

If you have accidentally taken a higher dose

If you have taken a higher dose, consult your physician. Symptoms of overdose may include nausea and headaches.

If you have taken an overdose, or if a child swallowed the medicine by mistake, refer immediately to the physician or to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take Fosrenol

It is important to take Fosrenol with every meal.

If you forgot to take this medicine at the proper time, take the next dose with your next meal.

Do not take a double dose to make up for a forgotten dose.

If you stop taking the medicine

Follow the treatment as recommended by the physician. Do not discontinue treatment with the medicine, even if there is an improvement in your condition, without consulting the physician.

Do not take medications in the dark! Check the label and dose every time you take a medicine. Use glasses if you need them for reading.

If you have further question about the use of this medicine, consult the physician or pharmacist.

4. Side Effects:

Like with any medicine, using **Fosrenol** can cause side effects in some of the users. Do not be alarmed when reading the list of side effects. You may experience none 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 in 10 people):

- Nausea, vomiting, diarrhoea, abdomen pain, headache, itching, rash.

Common side effects (may affect up to 1 in 10 people):

- 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 in 100 people):

Tiredness; feeling of discomfort; chest pain, weakness; swelling of 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; increase in certain liver enzymes, parathyroid hormone; increase in blood aluminium, calcium and glucose; increase or decrease in blood phosphates; thirst; weight loss; joint pain; muscle pain; weakness and thinning of the bones (osteoporosis); lack of and increased appetite; inflammation of the larynx; loss of hair; sweating increased; taste disturbance and increase in white blood cells count.

If any side effect appears, 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 Report" 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://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=adversEffectMedic@moh.gov.il>

5. How to Store the Medicine?

- Avoid poisoning! This medicine and all other medicines should be kept in a closed place out of the sight and reach of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
- Do not use this medicine after the expiry date (exp. date) stated on the package. The expiry date relates 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 doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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

White, round, flat tablets debossed with 'S405/500', 'S405/750' and 'S405/1000' on one side, for Fosrenol 500, 750 and 1000 respectively.

Carton packs containing bottles of the following quantities:

Fosrenol 500 – 45, 90 chewable tablets
Fosrenol 750 – 15, 90 chewable tablets
Fosrenol 1000 – 90 chewable tablets

It is possible that not all packs are marketed.

License holder:

Takeda Israel Ltd., 25 Eyal st.,

Petach Tikva 4951125

Manufacturer: Shire Pharmaceutical Contracts Ltd,
1 Kingdom Street, London, W2 6BD, UK

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Fosrenol 500 mg chewable tablets: 140 50 31968 00

Fosrenol 750 mg chewable tablets: 140 51 31998 00

Fosrenol 1000 mg chewable tablets: 140 52 31969 00

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