


FOSRENOL® 500 mg chewable tablets

FOSRENOL® 750 mg chewable tablets

lanthanum

Read all of this leaflet carefully before you start taking this medicine

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

In this leaflet:

1. What Fosrenol is and what it is used for
2. Before you take Fosrenol
3. How to take Fosrenol
4. Possible side effects
5. How to store Fosrenol
6. Further information

1. What FOSRENOL is and what it is used for

Fosrenol is used to lower the phosphate level in the blood of patients with chronic kidney disease.

Patients who have kidneys that do not work properly are not able to control the level of phosphate in the blood. The amount of phosphate in the blood then rises (your doctor may call this hyperphosphataemia).

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.

2. Before you take FOSRENOL**a. Do not take Fosrenol**

- if you are allergic (hypersensitive) to lanthanum carbonate hydrate or any of the other ingredients of Fosrenol;
- if you have too little phosphate in your blood (hypophosphataemia).

b. Take special care with Fosrenol

If you know that you have or have had any of the following conditions, you should discuss this with your doctor before using Fosrenol:

- stomach ulcer;
- ulcerative colitis;
- Crohn's disease;
- blockage of the bowel;
- reduced liver or kidney function.

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 have previously had abdominal surgery, or infection or inflammation of the abdomen/bowel (peritonitis) inform your doctor.

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

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

c. Taking other medicines, herbal or dietary supplements

Fosrenol can affect how certain medicines are absorbed from your digestive tract. If you are taking chloroquine (for rheumatism and malaria), ketoconazole (for fungal infections), tetracycline or doxycycline antibiotics they should not be taken within 2 hours before or after taking Fosrenol.

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

If you are taking levothyroxine (for an under active thyroid) it should not be taken within 2 hours before or after taking Fosrenol. Your doctor may want to monitor the levels of thyroid-stimulating hormone (TSH) in your blood more closely.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

d. Taking Fosrenol with food and drink

Fosrenol should be taken with, or immediately after food. The tablets should be chewed completely before swallowing. To aid in chewing the tablets may be crushed. Whole tablets should not be swallowed. Additional fluid is not necessary.

e. Pregnancy and breast-feeding

Fosrenol should not be taken during pregnancy. If you are, or could be pregnant, talk to your doctor before taking Fosrenol.

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.

f. Driving and using machines

Dizziness and vertigo (a feeling of dizziness or "spinning") are uncommon side effects reported by patients taking Fosrenol. If you experience these side effects it may affect your ability to drive or operate machinery.

g. Important information about some of the ingredients of Fosrenol

This product contains dextrates (sugars). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. May be harmful to the teeth.

3. How to take FOSRENOL

Always take Fosrenol exactly as your doctor or health care provider has told you. You should check with your doctor or pharmacist if you are not sure.

You should take Fosrenol with, or immediately after food. The tablets should be chewed completely before swallowing. To aid in chewing the tablets may be crushed. Whole tablets should not be swallowed. Additional fluid is not necessary.

Your doctor 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:

- Your diet (the amount of phosphate in the food you eat)
- Your blood phosphate level

To start with, the daily dose of Fosrenol will usually be 1 tablet with each meal (3 tablets per day).

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.

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 doctor as you may need to take extra Fosrenol. Your doctor will tell you what to do in this case.

a. If you take more Fosrenol than you should

If you take too many tablets contact your doctor to assess the risk and obtain advice. Symptoms of overdose may be nausea and headaches.

b. If you forget to take Fosrenol

It is important to take Fosrenol with every meal.

If you forget to take your Fosrenol tablets, then take the next dose with your next meal. Do not take a double dose to make up for a forgotten tablet.

4. Possible side effects

Like all medicines, Fosrenol can cause side effects, although not everybody gets them.

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

Very Common side effects (affect more than 1 in 10 people):

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

Common side effects (affects less than 1 in 10 people):

- Constipation, 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.

Please inform your doctor if you experience constipation. This can be an early symptom of a blockage in your intestine.

Uncommon side effects (affects less than 1 in 100 people):

- 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 gut or mouth
- loose stools
- increases in certain liver enzymes, parathyroid hormone, aluminium, 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
- increased white blood cell count

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store FOSRENOL

Keep out of the reach and sight of children.

Do not store above 30 °C. Store in the original container.

Do not use Fosrenol after the expiry date which is stated on the carton and the bottle label after EXP. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further Information**a. What Fosrenol contains**

The active substance is 500mg or 750mg lanthanum (as lanthanum carbonate hydrate).

The other ingredients are dextrates (hydrated), colloidal anhydrous silica and magnesium stearate.

b. What Fosrenol looks like and contents of the pack

Fosrenol is a white, round, bevelle-edged flat chewable tablet debossed with either S405/500® (500mg) or 'S405/750' (750mg) on one side of the tablet.

The tablets are supplied in packs of 90 tablets (500mg and 750 mg): 500mg 90's (45's HDPE Bottle x 2) 750mg 90's (15's HDPE Bottle x 6)

c. Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder is:

Shire Pharmaceutical Contracts Ltd., Hampshire International Business Park, Chineham, Basingstoke, Hampshire RG24 8EP, UK
The manufacturer is:

Hamol Limited, Thane Road, Nottingham, Nottinghamshire NG90 2DB, UK

d. This leaflet was last revised in 01/2015; version number 3**e. To report any side effect(s):****• Saudi Arabia:**

- National Pharmacovigilance and Drug Safety Center (NPC)
Call NPC at +966-11-2038222,
Exts: 2317-2356-2353-2354-2334-2340
• Fax: +966-11-205-7662
• Toll-free: 8002490000
• Email: npc.drug@sfd.gov.sa
• Website: www. sfd.gov.sa/npc

• United Arab Emirates:

- Ministry of Health
Registration and Drug Control Department
• Tel: +971-2-6117 389 / 329 / 391 / 318
• Fax: +971-2-6313742
• P.O. Box: 848 Abu Dhabi
• Email: pv@moh.gov.ae
• Website: www.cpd-pharma.ae

• Other GCC States:

- Please contact the relevant competent authority.

This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists