

FOSRENOL CHEWABLE TABLETS

Lanthanum carbonate hydrate (250mg, 500mg, 750mg & 1000mg)

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What Fosrenol 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).

How Fosrenol works

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.

Before you use Fosrenol

When you must not use it

Do not take Fosrenol:

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

Before you start to use it

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;
- inflammation of large intestine and rectum (ulcerative colitis);

- inflammation of the lining of the digestive system (Crohn's disease);
- blockage of the bowel;
- reduced liver or kidney function.

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.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

Fosrenol can affect how certain drugs 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.

If you are not sure about this, please check with your doctor or pharmacist as they will have a more complete and detail list of medicine which may interact with Fosrenol if taken together.

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 any medicines.

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.

How to use Fosrenol

How much to use

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 can be 750mg.

Every 2-3 weeks your doctor will check the level of phosphate in your blood and may adjust 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.

When to use it

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

How long to use it

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

If you forget to use it

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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 forgotten individual doses.

If you use too much (overdose)

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

While you are using it

Things you must do

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist

Things you must not do

- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours

Things to be careful of

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.

Side effects

Like all medicines, this medicine 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 greater than 1 in 10 people):

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

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 gullet or mouth; loose stools; increases in certain liver enzymes and parathyroid hormone; increased in 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 and taste disturbance.

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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and disposal of Fosrenol

Storage

Keep out of the reach and sight of children. Store below 25°C. Keep in the original container.

Do not use Fosrenol after the expiry date which is stated on the carton and the bottle

label. The expiry date refers to the last day of that month.

Disposal

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.

Product Description

What it looks like

Fosrenol is a white, round, bevelled flat chewable tablet embossed with either ‘S405/250’ (250mg), ‘S405/500’ (500mg), ‘S405/750’ (750mg) or ‘S405/1000’ (1000mg) on one side of the tablet.

The tablets are supplied in plastic bottles of 40, 90, 200, or 400 tablets (250mg); 20, 45, 90, 100, or 200 tablets (500mg); 15, 30, 45, 75, 90, or 150 tablets (750 mg); and 10, 15, 30, 50, 90, or 100 tablets (1000mg). Not all pack sizes may be marketed.

Ingredients

Active ingredients

The active substance is 250 mg, 500mg, 750mg or 1000mg lanthanum (as lanthanum carbonate hydrate).

Inactive ingredients

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

MAL No.:

250mg: MAL20081757AC
500mg: MAL20081758AC
750mg: MAL20081759AC
1000mg: MAL20081760AC

Manufacturer

Manufactured by:
Hamol Limited, Thane Road,
Nottingham, Nottinghamshire NG90
2DB, UK

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For:

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

Product Registration Holder

LF Asia (Malaysia) Sdn Bhd (719-V)
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Selangor Darul Ehsan

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