

Package Leaflet: Information for the Patient

FOSRENOL 250 mg chewable tablets
FOSRENOL 500 mg chewable tablets
FOSRENOL 750 mg chewable tablets
FOSRENOL 1000 mg chewable tablets

lanthanum

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Fosrenol is and what it is used for
2. What you need to know before you take Fosrenol
3. How to take Fosrenol
4. Possible side effects
5. How to store Fosrenol
6. Contents of the pack and other information

1. What Fosrenol is and what it is used for

Fosrenol is used to lower the phosphate level in the blood of adult 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 drug which reduces the body's absorption of phosphate from food by binding with it in your digestive tract. Phosphate which have bonded to Fosrenol cannot be absorbed through the intestinal wall.

2. What you need to know before you take Fosrenol

Do not take Fosrenol

- if you are allergic to lanthanum carbonate hydrate or any of the other ingredients of this medicine (listed in section 6).
- if you have too little phosphate in your blood (hypophosphataemia)

Warnings and precautions

Talk to your doctor or pharmacist before taking Fosrenol if you know that you have, or have had, any of the following:

- 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.

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

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.

Fosrenol with food and drink

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

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.

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.

3. How to take Fosrenol

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor 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. If you find chewing the tablets difficult, talk to your doctor as an oral powder form of this medicine is available.

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.

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.

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 dose.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets 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).

Other less serious side effects include the following:

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

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

Common side effects (may affect up to 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 (may affect up to 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, 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 and increased white blood cell count.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

5. How to store Fosrenol

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use this medicine 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.

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. Contents of the pack and other information

What Fosrenol contains

- The active substance is 250 mg, 500 mg 750 mg or 1000 mg lanthanum (as lanthanum carbonate hydrate).
- The other ingredients are dextrans (hydrated), colloidal anhydrous silica and magnesium stearate.

What Fosrenol looks like and contents of the pack

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

The tablets are supplied in plastic bottles of 90 tablets (250 mg); 20, 45 tablets, or a multipack containing 90 (2 packs of 45) chewable tablets (500 mg); 15, 45 tablets, or a multipack containing 90 (6 packs of 15) chewable tablets (750 mg); and 10, 15 tablets, or a multipack containing 90 (6 packs of 15) chewable tablets (1000 mg).

Not all pack sizes may be marketed.

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, Nottingham site, Thane Road, Nottingham, Nottinghamshire NG90 2DB, UK

Wasdell Packaging Limited, Units 1,2,3,5,6,7 & 8 Euro Way Industrial Estate, Blagrove, Swindon, SN5 8YW, UK

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

Shire Pharmaceuticals Limited, Hampshire International Business Park, Chineham, Basingstoke, Hampshire, RG24 8EP, UK. Tel: +44 (0) 800 055 6614.

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, UK	Fosrenol
Ireland, Italy	Foznol

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