

Package leaflet: Information for the patient

FOSRENOL 750 mg oral powder FOSRENOL 1000 mg oral powder

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
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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 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. 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)
- if you have blockage of the bowel (bowel obstruction).

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.

If you need to have a gastrointestinal endoscopy, please inform your doctor that you are taking Fosrenol because the endoscopist might detect lanthanum deposits in the digestive tract.

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 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 underactive 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 breastfeeding

Fosrenol should not be taken during pregnancy. If you are pregnant or breastfeeding, 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 medicine can be transferred to a child in breast milk, you should not breastfeed whilst taking Fosrenol. If you are breastfeeding, 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.

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 spoonfuls of soft food, taking care to see that the entire dose is mixed with the food. Ensure that the oral powder/food mixture is eaten immediately (within 15 minutes). Never store any oral powder/food mixture for use at a later time.

Your doctor will tell you how many sachets of oral powder you must take with each meal (your daily dose will be divided between meals). The number of sachets that you take will depend on:

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

Before starting on Fosrenol oral powder, your doctor may have used Fosrenol chewable tablets to find the correct dose. Fosrenol chewable tablets are available in a number of strengths allowing for smaller increases in dose. The starting dose of chewable tablets is usually 250 mg, three times a day with meals. Your dose of oral powder is likely to be 750 or 1000 mg, three times a day with meals. 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 and regularly thereafter.

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 much Fosrenol 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, 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).
- 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, stomach 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; 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.

Not known (frequency cannot be estimated from the available data):

- Product residue present in digestive tract

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible 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.

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store Fosrenol

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

This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton and the sachets after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines 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 lanthanum (as lanthanum carbonate hydrate). Each sachet contains lanthanum carbonate hydrate corresponding to 750 mg or 1000mg lanthanum.
- The other ingredients are dextrans (hydrated), colloidal anhydrous silica and magnesium stearate.

What Fosrenol looks like and contents of the pack

Fosrenol is presented as a white to off-white oral powder in a sachet.

The sachets are supplied in a carton of 90 sachets (outer carton contains 9 cartons of 10 sachets).

Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder is:

Takeda UK Ltd., 1 Kingdom Street, London, W2 6BD, UK.

The manufacturer is:

Catalent Germany Schorndorf GmbH, Steinbeisstr. 1 und 2, Schorndorf, Baden-Wuerttemberg, 73614, Germany

For any information about this medicine, please contact: medinfoemea@takeda.com

This medicine is authorised in the Member States of the **European Economic Area and in the United Kingdom (Northern Ireland)** under the following names:

Austria, Belgium, Denmark, Estonia, Finland, France, Germany, Iceland, Latvia, Luxembourg, Netherlands, Norway, Slovenia, Spain, Sweden, United Kingdom (Northern Ireland)	Fosrenol
Ireland, Italy	Foznol

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