Package leaflet: Information for the patient

FOZNOL 250 mg chewable tablets
FOZNOL 500 mg chewable tablets
FOZNOL 750 mg chewable tablets
FOZNOL 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 Foznol is and what it is used for

Foznol 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).

Foznol 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 Foznol cannot be absorbed through the intestinal wall.

2. What you need to know before you take Foznol

Do not take Foznol

- 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 Foznol 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.

It is very important to chew completely Foznol 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).

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 Foznol as it may affect the results.

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

Other medicines and Foznol

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

Foznol 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 Foznol.

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

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

Foznol with food and drink

Foznol should be taken with, or immediately after food. See section 3 for instructions on how to take Foznol.

Pregnancy and breastfeeding

Foznol 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 Foznol. 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 Foznol. If you experience these side effects, it may affect your ability to drive or operate machines.

Foznol 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 Foznol

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 Foznol with, or immediately after food. Side effects such as nausea and vomiting are more likely if you take Foznol 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 Foznol 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.

Foznol works by binding phosphate from the food in your gut. It is very important to take Foznol at every meal. If you change your diet, contact your doctor as you may need to take extra Foznol. Your doctor will tell you what to do in this case.

If you take more Foznol 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 Foznol

It is important to take Foznol with every meal.

If you forget to take your Foznol 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).
- Contact your doctor if you experience new or severe constipation, it could be an early sign of a 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.

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5. How to store Foznol

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 bottle label 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 Foznol contains

- The active substance is lanthanum (as lanthanum carbonate hydrate). Each chewable tablet contains lanthanum carbonate hydrate corresponding to 250 mg, 500 mg, 750 mg, or 1000 mg lanthanum.

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

What Foznol looks like and contents of the pack

Foznol is presented as 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:

Takeda Pharmaceuticals International AG Ireland Branch,
Block 2 Miesian Plaza,
50 – 58 Baggot Street Lower
Dublin 2, D02 HW68, Ireland
Tel: + 800 6683 8470
E-mail: medinfoEMEA@takeda.com

The manufacturer is:

RB NL Brands B.V., Schiphol Boulevard 207, 1118BH, Schiphol, Netherlands.

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, Bulgaria, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Latvia, Lithuania, Luxembourg, Netherlands, Norway, Poland, Slovakia, Slovenia, Spain, Sweden, United Kingdom (Northern Ireland)	Fosrenol
Ireland, Italy, Malta	Foznol

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