

FOSRENOL®
Lanthanum carbonate hydrate
500 mg, 750 mg, 1000 mg
Chewable Tablets

Consumer Medicine Information

Read this leaflet carefully before you start taking this medicine.

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

What is this leaflet?

This leaflet answers some common questions about FOSRENOL chewable tablets. It does not contain all of the available information.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given FOSRENOL against the benefits they expect it will have for you. If you have any concerns about being given FOSRENOL, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What FOSRENOL is used for

FOSRENOL is a drug which reduces the body's absorption of phosphate from food by binding in the digestive tract. Phosphate which is bonded to FOSRENOL cannot be absorbed through the intestinal wall.

Patients who have kidneys that do not work properly are not able to control the level of phosphate in their blood. The amount of

phosphate in the blood then rises (your doctor will call this hyperphosphataemia). FOSRENOL is used to lower the phosphate level in the blood of these patients.

Before you take FOSRENOL

FOSRENOL chewable tablets are not suitable for everyone.

When you must not be given it

Do not take FOSRENOL:

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

Before you are given it

If you know that you have reduced liver function, you should discuss this with your doctor before using FOSRENOL. It is possible that your liver will not be able to "clean" FOSRENOL from your body adequately.

Taking FOSRENOL with food and drink: FOSRENOL should be taken with, or immediately after, food. The tablets should be chewed completely and not swallowed whole.

Pregnancy:

You should not use FOSRENOL during pregnancy unless your doctor considers it absolutely necessary.

Breast-feeding:

Some medicines can have harmful effects on the breast feeding baby. FOSRENOL may be passed into breast milk and therefore is not recommended for mothers who breast feed their babies.

Taking other medicines

As FOSRENOL can affect the uptake of certain drugs from the digestive tract, these drugs should not be taken at least 2 hours

before or after taking FOSRENOL. The following drugs for example are affected:

- chloroquine (against rheumatism and malaria)
- Ketokonazole (against fungal infections)
- Certain antibiotics (tetracycline, doxycycline or floxacins)

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even any that you buy without a prescription from your pharmacy, supermarket or health food shop.

How FOSRENOL is given

Always take FOSRENOL exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

You should take FOSRENOL with, or immediately after, meals. The tablets must be chewed.

How much is given

Your doctor will tell you how many tablets you must take with each meal (your daily dose will be divided between three 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). Your doctor will then check the level of phosphate in your blood and may then increase this dose to a level that is correct for you.

FOSRENOL works by binding phosphate from the food in your gut. It is very important to take FOSRENOL at every meal. If you eat extra meals, or eat between meals, you may need to take extra FOSRENOL. Your doctor, dietician or nurse will tell you what to do in this case.

How long it is given

Your doctor will decide how long to continue your treatment with FOSRENOL.

Overdose

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much FOSRENOL tablets. Do this even if there are no signs of discomfort or poisoning.

Symptoms of overdose may include 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 forgotten individual doses.

While you are being given FOSRENOL

Things you must do

Keep all of your doctor's appointments so your progress can be checked.

Tell all doctors, dentists and pharmacists who are treating you that you are having treatment with FOSRENOL.

Remind them if any new medicines are about to be started, or if you are about to have a medical or dental procedure.

Like most medicines FOSRENOL is not recommended during pregnancy or while breastfeeding. It is uncertain whether or not FOSRENOL can affect the unborn child. If it is necessary for you to receive this medicine, your doctor will discuss the risks and benefits of taking FOSRENOL.

If pregnancy occurs during your treatment, you must immediately inform your doctor.

Things that you must not do

Do not use any other medicines while using FOSRENOL unless you have discussed this with your doctor or pharmacist. This includes medicines you can buy without a prescription from a pharmacy, supermarket or health food shop.

Do not use FOSRENOL to treat any complaint other than directed by your doctor. It may not be safe to use FOSRENOL for another complaint.

FOSRENOL should only be used by or for the person for whom it was prescribed. Do not administer FOSRENOL to someone else even if the symptoms are the same. It may not be safe for another person to use FOSRENOL.

Things to be careful of

No effects of FOSRENOL on the ability to drive and use machines have been observed.

Side Effects

Like all medicines, FOSRENOL can have side effects. Stomach effects are more likely if you take FOSRENOL before your meal. You should always take it during or immediately after your food.

Common side effects (occur in more than 1 patient out of 100) include nausea, vomiting, dialysis graft complication, diarrhoea, headache, dialysis graft occlusion, stomach pain, hypotension, constipation, bronchitis and rhinitis.

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 (occur in less than 1 patient out of 100) include tiredness; feeling of discomfort; chest pain, weakness; swollen hands and feet; body pain; dizziness; headache; vertigo; belching; inflammation of the stomach and intestines; indigestion; irritable bowel syndrome; dry mouth; 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; itching; rash; increased sweating; taste disturbance and increased white blood cell count.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell. Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using FOSRENOL

Storage

- Keep FOSRENOL where children cannot reach it.
- Store FOSRENOL below 25°C.
- Do not use FOSRENOL after the expiry date stated on the bottle label.

Disposal

Return any unused medicine to your pharmacist.

Product Description

What FOSRENOL looks like

FOSRENOL chewable tablets are available in the following strengths and pack sizes:

FOSRENOL 500 mg: White, round, bevel-edged flat tablets embossed with 'S405/500'

on one side (45 tablets per bottle; 2 bottles per carton).

FOSRENOL 750 mg: White to off-white round, flat bevelled edge tablets embossed on one side with 'S405' above '750' (15 tablets per bottle; 6 bottles per carton).

FOSRENOL 1000 mg: White to off-white round, flat bevelled edge tablets embossed on one side with 'S405' above '1000' (15 tablets per bottle; 6 bottles per carton).

Ingredients

FOSRENOL® chewable tablets, lanthanum carbonate hydrate:

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

Sponsor

FOSRENOL® is distributed in Australia by:

Orphan Australia Pty. Ltd.
48 Kangan Drive
Berwick, Victoria 3806
www.orphan.com.au

Under licence from:

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

Australian Registration Numbers:

FOSRENOL 500 mg, 2 bottles of 45 tablets
AUST R 106960

FOSRENOL 750 mg, 6 bottles of 15 tablets
AUST R 106962

FOSRENOL 1000 mg, 6 bottles of 15 tablets
AUST R 106964

FOSRENOL® is a registered trademark of Shire Pharmaceutical Contracts Ltd, UK, used under licence by Orphan Australia Pty. Ltd.

This leaflet was prepared in August 2007.