

FOSRENOL®

500 mg, 750 mg, 1000 mg Chewable Tablets

Lanthanum carbonate hydrate

Consumer Medicine Information

What is in this leaflet

Please read this leaflet before you start taking FOSRENOL.

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

This information is not intended to replace the advice of your health care professional.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking FOSRENOL against the benefits they expect it will have for you.

If you have any concerns about taking FOSRENOL, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What FOSRENOL is used for

Phosphorus is found in your body as "Phosphate" and is needed for building strong teeth and bones as well as keeping other parts of your body healthy. When your kidneys fail to work properly, phosphate can build up in the blood. This build up of excess phosphate is called hyperphosphataemia.

FOSRENOL is a phosphate binder and is used to lower the amount of phosphate in your body. It prevents the body from absorbing the phosphate from the food you eat.

The phosphate in the food binds to FOSRENOL and is carried through

the digestive tract to be eliminated in your stool.

FOSRENOL tablets are not addictive.

FOSRENOL tablets are only available on a doctor's prescription.

Before you take FOSRENOL

FOSRENOL chewable tablets are not suitable for everyone.

When you must not take FOSRENOL

Do not take FOSRENOL if:

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

Before you start to take FOSRENOL

You must tell your doctor if:

- you have reduced liver function. It is possible that your liver will not be able to "clean" FOSRENOL from your body adequately
- you have disease involving the gastrointestinal tract
- you have Crohn's disease
- you have ulcerative colitis
- you have or have had a stomach ulcer

- you have or have had a blockage of the bowel
- you have previously had abdominal surgery, or infection or inflammation of the abdomen/bowel (peritonitis)
- you are pregnant or plan to become pregnant
- you are breast-feeding. Some medicines can have harmful effects on the breast fed baby. FOSRENOL may be passed into breast milk and therefore is not recommended for mothers who breast feed their babies.

If you have not told your doctor about any of the above, tell them before you start taking FOSRENOL.

Taking other medicines

Tell 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.

FOSRENOL and some medicines may interfere with each other.

FOSRENOL can affect the uptake of certain medicines from the gut.

Such medicines should be taken at least 2 hours before or 2 hours after taking FOSRENOL.

The following drugs are affected:

- chloroquine (against rheumatism and malaria)
- ketoconazole (against fungal infections)
- thyroxine (used for deficiency of thyroid hormone)

- certain antibiotics (tetracycline, doxycycline)

Quinolone antibiotics such as ciprofloxacin and norfloxacin should be taken at least two hours before or four hours after FOSRENOL.

How to take FOSRENOL

Always take FOSRENOL exactly as your doctor has instructed you.

You should check with your doctor or pharmacist if you are unsure as to how you should take FOSRENOL.

How much to take

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.

How to take it

FOSRENOL tablets must be chewed completely and not swallowed whole.

For those patients who have dentures or those who have difficulty chewing you can crush the tablets.

When to take it

FOSRENOL works by binding phosphate from the food in your gut.

It is very important to take FOSRENOL during or immediately after every meal.

If you eat extra meals, or eat between meals, you may need to

take extra FOSRENOL. Your doctor will tell you what to do in this case.

How long to take it

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

If you forget to take it

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 forgotten doses.

If you take too much (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.

Do this even if there are no signs of discomfort or poisoning.

Symptoms of overdose may include nausea, vomiting and headaches.

While you are taking 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.

If you need to have an x-ray of your stomach or abdomen, please tell your doctor that you are taking Fosrenol as it may affect the results of the x-ray.

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 you must not do

Do not use any other medicines while taking 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 the person for whom it was prescribed. Do not administer FOSRENOL to someone else even if they have the same condition as you.

It may not be safe for another person to use FOSRENOL.

Things to be careful of

Dizziness and vertigo (a feeling of dizziness or "spinning") are uncommon side effects reported by some patients taking FOSRENOL. If you experience these side effects it may affect your ability to drive or operate machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well whilst you are taking FOSRENOL

Like all medicines, FOSRENOL can have side effects. Sometimes they are serious, most of the time

they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Tell your doctor if you notice any of the following and they worry you:

- nausea
- vomiting
- diarrhoea
- headache
- stomach pain
- constipation
- bronchitis and rhinitis
- dizziness (from low blood pressure)

The above list includes the more common side effects of FOSRENOL. They are usually mild. Stomach effects are more likely if you take FOSRENOL before your meal.

You should always take FOSRENOL during or immediately after your food.

Hypocalcaemia (too little calcium in your blood) is also a common side effect. The symptoms of hypocalcaemia can include tingling in the hands and feet, muscle and abdominal cramps or spasms of the facial and feet muscles. Because severe hypocalcaemia can be serious, tell your doctor if you have any of the symptoms described above.

Some people get other less common side effects whilst taking FOSRENOL. These may include:

- tiredness
- chest pain
- weakness
- dry mouth
- weight decrease
- thinning of the bones (osteoporosis)
- joint pain
- loss of hair
- itching; rash
- increase sweating
- taste disturbance

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using FOSRENOL

Storage

Keep your medicine in the original pack until it is time to take it.

Keep FOSRENOL where children cannot reach it.

A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

Keep your medicine in a cool, dry place where the temperature stays below 25°C.

Do not store FOSRENOL or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Do not take FOSRENOL after the expiry date stated on the bottle label.

Disposal

Ask your pharmacist what to do with any unwanted medicine that is left over or if the expiry date has passed.

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 debossed 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 debossed 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 debossed on one side with 'S405' above '1000' (15 tablets per bottle; 6 bottles per carton).

Ingredients

FOSRENOL contains 500 mg, 750 mg or 1000 mg lanthanum as the active substance in form of lanthanum carbonate hydrate.

The other ingredients are:

- dextrans
- silicon dioxide
- magnesium stearate

Supplier

Shire Australia Pty Limited
Level 39
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Sydney, NSW 2000
Australia

Phone: 1800 012 612

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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

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