

Fosrenol®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I taking FOSRENOL?

FOSRENOL contains the active ingredient lanthanum carbonate hydrate. FOSRENOL is used to lower the phosphate level in the blood of adult patients with chronic kidney disease.

For more information, see Section [1. Why am I taking FOSRENOL?](#) in the full CMI.

2. What should I know before I take FOSRENOL?

Do not use if you have ever had an allergic reaction to FOSRENOL or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take FOSRENOL?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with FOSRENOL and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take FOSRENOL?

- Always take this medicine exactly as your doctor or pharmacist has told you
- FOSRENOL tablets must be chewed completely and not swallowed whole. Patients who have chewing difficulty, the tablets can be crushed.
- FOSRENOL should be taken with or immediately after food.

More instructions can be found in Section [4. How do I take FOSRENOL?](#) in the full CMI.

5. What should I know while taking FOSRENOL?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, or pharmacist you visit or any new medicines you are about
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	<p>to start, that you are using FOSRENOL.</p> <ul style="list-style-type: none"> ● If you need to have an X-ray or an endoscopy, please inform your doctor that you are taking FOSRENOL, as it may affect the results.
Things you should not do	<ul style="list-style-type: none"> ● Do not use any other medicines while taking FOSRENOL unless you have discussed this with your doctor or pharmacist. ● FOSRENOL tablets must be chewed completely and not swallowed whole.
Driving or using machines	<ul style="list-style-type: none"> ● Dizziness, nausea, and vertigo are uncommon side effects of FOSRENOL; which may affect your ability to drive or operate machinery.
Looking after your medicine	<ul style="list-style-type: none"> ● Keep your medicine in a cool, dry place where the temperature stays below 25°C

- Keep FOSRENOL where children cannot reach it.

For more information, see Section [5. What should I know while taking FOSRENOL?](#) in the full CMI.

6. Are there any side effects?

The common side effects include nausea, vomiting, diarrhoea, headache, stomach pain, constipation, itching, skin rash, low calcium (hypocalcaemia), blockage in the intestine.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

FOSRENOL®

Active ingredient: *lanthanum carbonate hydrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using FOSRENOL. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using FOSRENOL.**

Where to find information in this leaflet:

- [1. Why am I taking FOSRENOL?](#)
- [2. What should I know before I take FOSRENOL?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take FOSRENOL?](#)
- [5. What should I know while taking FOSRENOL?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking FOSRENOL?

FOSRENOL contains the active ingredient lanthanum carbonate hydrate.

Phosphorous 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 buildup 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.

2. What should I know before I use FOSRENOL?

FOSRENOL chewable tablets are not suitable for everyone.

Do not use FOSRENOL if:

- you are allergic to lanthanum carbonate, or any of the ingredients listed at the end of this leaflet
- always check the ingredients to make sure you can use this medicine
- you have bowel blockage (obstruction), no movement in your bowels (ileus), or you are unable to defecate due to faecal impaction
- you have too little phosphate in your blood (hypophosphataemia).

Check with 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
- a disease involving the gastrointestinal tract
- inflammatory bowel disease including ulcerative colitis or Crohn's disease
- a history of stomach ulcer
- a history of blockage of the bowel
- previously had abdominal surgery, or infection or inflammation of the abdomen/bowel (peritonitis)
- reduced kidney function
- taken any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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.

Warnings

- It is very important to chew completely FOSRENOL tablets and not to swallow them whole or incompletely chewed. This will reduce the risk of adverse gastrointestinal complications like rupture in the intestinal wall, blockage in the intestine, constipation (see also section 6).
- 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 it might detect lanthanum deposits in the digestive tract.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins, or supplements that you buy without a prescription from your pharmacy, supermarket, or health food shop.

Some medicines may interfere with FOSRENOL and affect how it works.

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)
- certain antibiotics (tetracycline, doxycycline)
- thyroxine (used for deficiency of thyroid hormone).

Quinolone antibiotics such as ciprofloxacin and norfloxacin should be taken at least 2 hours before or four hours after FOSRENOL.

4. How do I take FOSRENOL?

How much to take

Always take FOSRENOL exactly as your doctor has instructed you.

- 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.

When to take FOSRENOL

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 to take FOSRENOL

- 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.

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 the dose you missed.**

If you took too much FOSRENOL

If you think that you have taken too much FOSRENOL, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or

- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

Symptoms of overdose may include nausea, vomiting and headaches. **You should do this even if there are no signs of discomfort or poisoning.**

5. What should I know while taking FOSRENOL?

Things you should do

Keep all 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.

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.

Like most medicines FOSRENOL is not recommended during pregnancy or while breastfeeding. It is uncertain whether 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 should not do

- Do not stop using this medicine suddenly. Your doctor will decide how long to continue your treatment with FOSRENOL.
- 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how FOSRENOL affects you.

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.

Looking after your medicine

Keep your medicine in the original pack until it is time to take it. Keep your medicine in a cool, dry place where the temperature stays below 25°C.

For example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• nausea• vomiting• diarrhoea• headache• stomach pain• Indigestion• flatulence• constipation• bronchitis and rhinitis• dizziness (from low blood pressure)• tiredness• weakness• dry mouth• weight decrease	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>Stomach side effects are more likely if you take FOSRENOL before your meal.</p> <p>You should always take FOSRENOL during or immediately after your food.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● thinning of the bones (osteoporosis) ● joint pain ● loss of hair ● itching; skin rash ● increase sweating ● taste disturbance ● reduced appetite ● swelling ankles 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> ● blockage in the intestine: symptoms include severe bloating, severe abdominal pain, swelling or cramps; severe constipation ● hypocalcaemia (too little calcium in your blood) symptoms include tingling in the hands and feet, muscle and abdominal cramps or spasms of the facial and feet muscles 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> • chest pain 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What FOSRENOL contains

Active ingredient	500 mg, 750 mg, or 1000 mg of lanthanum as lanthanum carbonate hydrate.
Other ingredients	Dextrates, silicon dioxide, magnesium stearate

Do not take this medicine if you are allergic to any of these ingredients.

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).

Australian Registration Numbers

- AUST R 106960 (FOSRENOL 500 mg)

- AUST R 106962 (FOSRENOL 750 mg)
- AUST R 106964 (FOSRENOL 1000 mg)

Not all pack sizes may be supplied.

Who distributes FOSRENOL

Takeda Pharmaceuticals Australia Pty Ltd

Level 39

225 George Street

Sydney, NSW 2000

Australia

www.takeda.com/en-au

Phone: 1800 012 612

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