

MEDICATION GUIDE
FOSRENOL® (foss-wren-all)
(lanthanum carbonate)
Chewable Tablets

Read this Medication Guide before you start taking FOSRENOL and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

What is the most important information I should know about FOSRENOL?

FOSRENOL may cause a bowel blockage or severe constipation which can be serious, and sometimes lead to surgery or treatment in a hospital.

- You may have a higher risk of bowel blockage or severe constipation if you take FOSRENOL and have:
 - a history of bowel surgery or colon cancer
 - a history of bowel blockage, decreased movement of your bowel, constipation, or diabetes

Do not swallow FOSRENOL Chewable Tablets whole. Chew tablets completely before swallowing. If you can not chew tablets completely, you may crush the tablets thoroughly before swallowing.

What is FOSRENOL?

FOSRENOL is a prescription medicine used in people with end stage renal disease (ESRD) to lower the amount of phosphate in the blood.

Who should not take FOSRENOL?

Do not take FOSRENOL if you:

- have blocked bowels
- have severe constipation

FOSRENOL has not been studied in children and adolescents under 18 years of age.

What should I tell my healthcare provider before taking FOSRENOL?

FOSRENOL may not be right for you. Before starting FOSRENOL, tell your healthcare provider if you:

- have a history of bowel surgery or colon cancer

- have a history of a bowel blockage, ileus or constipation, or diabetes
- have stomach ulcers, ulcerative colitis, or Crohn's disease
- plan to have an x-ray of your stomach (abdomen)
- have any other medical conditions
- are pregnant, plan to become pregnant, or plan to breastfeed. It is not known if FOSRENOL will harm your unborn baby

Tell your healthcare provider about all of the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Especially tell your healthcare provider if you take:

- antacids
- antibiotics
- thyroid medicine

Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I take FOSRENOL?

- Take FOSRENOL exactly as prescribed by your healthcare provider
- Your healthcare provider will tell you how much FOSRENOL to take
- Your healthcare provider may change your dose if needed
- **Do not swallow tablets whole. Chew tablets completely before swallowing. If you cannot chew tablets completely, or if you have tooth disease, you may crush the tablets thoroughly before swallowing**
- Take FOSRENOL with or right after meals
- If you take an antacid medicine, take the antacid 2 hours before or 2 hours after you take FOSRENOL
- If you take medicine for your thyroid (levothyroxine), take the thyroid medicine 2 hours before or 2 hours after you take FOSRENOL
- If you take an antibiotic medicine, take the antibiotic 1 hour before or 4 hours after you take FOSRENOL

What are possible or reasonably likely side effects of FOSRENOL?

See **“What is the most important information I should know about FOSRENOL?”**

The most common side effects of FOSRENOL include:

- nausea
- vomiting
- diarrhea
- stomach pain

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the side effects of FOSRENOL. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store FOSRENOL?

- Store FOSRENOL between 59°F to 86°F (15°C to 30°C).
- Keep FOSRENOL tablets dry.

Keep FOSRENOL and all medicines out of the reach of children.

General information about FOSRENOL

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use FOSRENOL for a condition for which it was not prescribed. Do not give FOSRENOL to other people, even if they have the same condition. It may harm them.

This Medication Guide summarizes the most important information about FOSRENOL. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about FOSRENOL that is written for healthcare professionals.

For more information go to www.FOSRENOL.com or call 1-800-828-2088.

What are the ingredients in FOSRENOL?

Active ingredient: lanthanum carbonate

Inactive ingredients: colloidal silicon dioxide NF, and magnesium stearate NF.

This Medication Guide has been approved by the US Food and Drug Administration.

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IMPORTANT DRUG WARNING

Date

Document Reference Number

Re: Addition of gastrointestinal obstruction, ileus and fecal impaction as contraindications, and addition of tooth injury as a post-marketing adverse reaction to the use of FOSRENOL (lanthanum carbonate)

Dear Healthcare Professional (Nephrologists, Renal Dieticians, Dialysis Nurses)

FOSRENOL is indicated to reduce serum phosphate in patients with end stage renal disease. We want to make you aware of important changes to the labeling for FOSRENOL that relate to patient safety.

Contraindications to the use of FOSRENOL:

- bowel obstruction
- ileus
- fecal impaction

Adverse Reaction:

- tooth injury

Risk Minimization:

- FOSRENOL must not be administered to patients with bowel obstruction, ileus, or fecal impaction
- Tablets should be chewed or crushed completely before swallowing
- Intact tablets must not be swallowed
- Advise patients with poor dentition that they may crush tablets completely

There have been reports of serious cases of gastrointestinal obstruction, ileus, and fecal impaction reported in association with lanthanum, some requiring surgery or hospitalization.

Risk factors for gastrointestinal obstruction identified from post-marketing reports include alteration in gastrointestinal anatomy (e.g., history of gastrointestinal surgery, colon cancer), hypomotility disorders (e.g., constipation, ileus, diabetes) and concomitant medications (e.g., calcium channel blockers). Some cases were reported in patients with no history of gastrointestinal disease.

Cases of tooth injury with lanthanum carbonate tablet administration, identified from post-marketing experience, have been observed as well. Some of these have been associated with patient reports of tablet hardness/tablet difficult to chew. Additionally, reports of tablet hardness/tablet difficult to chew but without tooth injury have also been received. The majority of patients with an event reported while chewing the tablets as recommended were elderly (≥ 60 years of age).

Lanthanum carbonate tablets must be chewed or crushed completely and not swallowed whole.

Important Safety Information:

- FOSRENOL is contraindicated in patients with bowel obstruction, ileus and fecal impaction
- Serious cases of gastrointestinal obstruction, ileus, and fecal impaction have been associated with lanthanum use, some requiring surgery or hospitalization. Risk factors include constipation and altered gastrointestinal anatomy
- Advise patients to chew or crush the tablet completely to reduce the risk of adverse gastrointestinal events. Advise patients with poor dentition that they may crush tablets completely
- Patients with acute peptic ulcer, ulcerative colitis, Crohn's disease, or bowel obstruction were not included in FOSRENOL clinical studies
- FOSRENOL has radio-opaque properties and may give the appearance typical of an imaging agent during abdominal X-ray procedures
- The most common reactions seen with FOSRENOL included nausea, vomiting, diarrhea, and abdominal pain
- The following adverse reactions have been identified during post-approval use of FOSRENOL: constipation, dyspepsia, allergic skin reactions, hypophosphatemia, and tooth injury
- There is potential for FOSRENOL to interact with (1) compounds that bind to cationic antacids (i.e., aluminum-, magnesium-, or calcium-based agents), (2) oral quinolone antibiotics, and (3) thyroid replacement therapy; therefore, such concomitant medications should be dosed separately from FOSRENOL to avoid drug interactions. See specific dosing recommendations in the full Prescribing Information

- No adequate and well-controlled studies have been conducted in pregnant women and pediatric patients. FOSRENOL is not recommended for use during pregnancy
- The safety of lanthanum carbonate excreted in human milk is unknown. Caution should be exercised when FOSRENOL is administered to a nursing woman
- The use of FOSRENOL in the pediatric population is not recommended

If you have any questions about FOSRENOL, please contact Shire at 1-800-828-2088. To report adverse reactions associated with FOSRENOL, please call Shire on 1-866-470-5858 or e-mail globalpharmacovigilance@shire.com.

Also you are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch or call 1-800-FDA-1088.

Please see the accompanying Full Prescribing Information for FOSRENOL included with this mailing that has these changes incorporated.

The content of this letter has been reviewed and agreed to by the FDA.

Sincerely,