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 <u>www.FOSRENOL.com</u> or call 1-800-828-2088.

What are the ingredients in FOSRENOL?

Active ingredient: lanthanum carbonate

Inactive ingredients: colloidal silicon dioxide NF, dextrates (hydrated) NF, and magnesium stearate NF.

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

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