


PART III: CONSUMER INFORMATION


FOSRENOL^{®*}
 (lanthanum carbonate hydrate)

This leaflet is Part III of a three-part "Product Monograph" published when FOSRENOL was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about FOSRENOL. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

- To reduce phosphorus levels in patients with end stage renal disease who are on dialysis.

What it does:

FOSRENOL reduces the absorption of phosphate from food by binding the phosphate in the gut.

When it should not be used:

You should not take FOSRENOL

- If you have blocked bowels.
- If you have severe constipation.
- You have low blood phosphate levels (hypophosphatemia).
- If you are allergic to any of the ingredients in FOSRENOL (see "What the medicinal ingredient is" and "What the important non medicinal ingredients are").

What the medicinal ingredient is:

Lanthanum carbonate hydrate

What the important nonmedicinal ingredients are:

Colloidal silicon dioxide, dextrates (hydrated) and magnesium stearate.

What dosage forms it comes in:

Chewable Tablets. Each chewable Tablet contains 250mg, 500mg, 750mg or 1000mg of lanthanum as lanthanum carbonate hydrate.

WARNINGS AND PRECAUTIONS

BEFORE you use FOSRENOL talk to your doctor or pharmacist if:

- You have a history of bowel blockage, ileus, constipation, or diabetes
- You have had previous abdominal surgery
- You have suffered from peritonitis (inflammation of the abdomen)
- You suffer from acute peptic ulcer, ulcerative colitis, or Crohn's disease
- You suffer from liver impairment or biliary obstructions

- You are taking chelation therapy
- You are pregnant, planning to get pregnant or nursing.

Tell your doctor that you are taking FOSRENOL before having an X-ray of your stomach (abdomen), as this may affect the results.

You should also be aware that:

- FOSRENOL is not for use in children under 18 years of age
- Experience with therapy beyond 2 years is limited
- Bone lanthanum accumulation has been shown in animals and humans.

INTERACTIONS WITH THIS MEDICATION

Drugs known to interact with antacids should not be taken within 2 hours before or after taking FOSRENOL (e.g., tetracycline, doxycycline, chloroquine, hydroxychloroquine and ketoconazole).

It is not recommended that you take oral floxacin antibiotics (including ciprofloxacin) simultaneously with FOSRENOL.

If you are taking thyroxine (for an underactive thyroid), do not take it simultaneously with FOSRENOL; your doctor may want to monitor blood levels of thyroid-stimulating hormone (TSH) more closely.

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines even those not prescribed.

PROPER USE OF THIS MEDICATION**Usual Dose:**

Usual starting daily dose is between 750mg to 1500mg, to be taken in divided doses and with or immediately after a meal. The dose may be adjusted every 2 to 3 weeks. Most patients require a daily dose between 1500mg and 3000mg.

The tablet should be chewed completely before swallowing. Do not swallow tablets whole.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose, then take the next scheduled dose at your following meal. Taking a dose at a time other than mealtime may lead to nausea and vomiting. Do not double dose to catch up.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The most common adverse events in clinical trials were gastrointestinal such as nausea and vomiting.

You may also experience:

Dialysis graft complications, indigestion or heartburn, diarrhea or soft stool, headache, constipation, respiratory infection, infection of the throat, infection of the membrane of the nose, high blood sugar levels, low or high blood phosphate levels, loss of appetite, increased appetite, dizziness, strange tastes, trouble with digestive system, gas, dry mouth, difficulty swallowing, sores in the mouth, tooth disorder, tooth injury, losing some hair, itching, redness of skin, rash, increased sweating, muscle and joint pain, fatigue, malaise, pain, thirst, increased liver enzyme levels, increased blood aluminium levels, and weight decrease.

To reduce side effects such as nausea, vomiting, abdominal cramps and diarrhea, take FOSRENOL with or immediately after a meal.

HOW TO STORE IT

Store between 15-25°C; excursions permitted up to 30°C. Protect from moisture.

Keep in a safe place out of the reach of children and pets.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701D
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be provided by contacting the sponsor, Shire Canada Inc. at: 1-800-268-2772.

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This leaflet was prepared by Shire Canada Inc.

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SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / Effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Very common	Allergic skin reaction (including rashes, hives and itching)		√	
Common	Hypotension (low blood pressure)		√	
Uncommon	Chest pain		√	
	Eosinophilia (abnormal white blood cell count)		√	
	Hyperparathyroidism (enlarged parathyroid glands)		√	
	Hypocalcemia (low blood calcium levels)		√	
	Osteoporosis (Bone Disease)		√	
	Peripheral edema (swelling of limbs)		√	

This is not a complete list of side effects. For any unexpected effects while taking FOSRENOL, contact your doctor or pharmacist.