

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

Pr**VELPHORO**[®]
Sucroferric Oxyhydroxide Chewable tablet

Read this carefully before you start taking **Velphoro** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Velphoro**.

What is Velphoro used for?

To control high phosphorus levels in adult patients who have end stage kidney disease and are on dialysis.

How does Velphoro work?

Velphoro lowers phosphorus levels in the blood. It helps prevent as much phosphorus from being absorbed into your blood from the foods you eat.

What are the ingredients in Velphoro?

Medicinal ingredients: sucroferric oxyhydroxide (a mixture of polynuclear iron(III)-oxyhydroxide, sucrose, pregelatinized maize starch and potato starch).

Non-medicinal ingredients: magnesium stearate, neohesperidin dihydrochalcone, silica (colloidal, anhydrous), and woodberry flavour.

Velphoro comes in the following dosage forms:

Chewable tablets, 500 mg iron (equivalent to 2500 mg sucroferric oxyhydroxide).

Do not use Velphoro if:

- You are allergic to
 - sucroferric oxyhydroxide (active substance of Velphoro) or
 - any of the other ingredients in Velphoro.
- You have a history of abnormal iron build-up in your body (hemochromatosis).
- You have any other disorder where there is a build-up of iron in your body.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Velphoro. Talk about any health conditions or problems you may have, including if you:

- have a condition where you have problems digesting sugars, such as fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency. Velphoro contains sugars and starches that can be digested to glucose, fructose, and maltose.
- have diabetes. One tablet of Velphoro contains about 1.4 g of carbohydrates.
- have had an inflammation of the thin tissue that lines the abdominal wall and covers each organ (peritonitis).
- have major stomach and/or liver problems.
- have had major surgery on your stomach or intestines.
- are pregnant or nursing, or think you may be pregnant or are planning to have a baby.

Other warnings you should know about:

- Velphoro can cause diarrhea, which may become less common with continued treatment.
- Velphoro can cause black stools. This may hide bleeding from your stomach and intestines. Contact your healthcare professional immediately if you are getting more tired and breathless. This may be a sign of bleeding from your stomach or intestines.
- While you are taking Velphoro, your healthcare professional will monitor your phosphorus and iron levels through blood tests. Your dose of Velphoro may need to be adjusted depending on the results of the tests.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Velphoro:

- alendronate, used to prevent and treat osteoporosis (bone loss)

If you are taking this medicine, take it at least one hour before taking Velphoro.

- doxycycline, an antibiotic

If you are taking this medicine, take it at least one hour before taking Velphoro or at least two hours after taking Velphoro.

- levothyroxine, used to treat low thyroid levels

If you are taking this medicine, take it at least one hour before taking Velphoro.

How to take Velphoro:

- Always take this medicine exactly as your healthcare professional has told you. Talk to your healthcare professional if you are not sure.
- Velphoro is a chewable tablet. DO NOT swallow it whole without chewing the tablet first. You can crush the tablet into smaller pieces to make it easier for you to chew and swallow.
- Always take Velphoro with a meal. Divide your daily number of tablets across the meals you eat each day. For example:
 - if you take three tablets a day, take one tablet with each meal (breakfast, lunch and supper).
 - if you take 4 tablets in a day, divide them so that you take 2 tablets with your main meal and one tablet at each of your remaining meals.

Usual dose:

- Usual starting dose:
 - 3 tablets (1,500 mg) per day.
 - Take one tablet (500 mg) with each meal (breakfast, lunch and supper).
- Your healthcare professional will monitor the amount of phosphorus in your blood through regular blood tests. Your dose may need to be adjusted until the amount of phosphorus in your blood is acceptable.
- The maximum recommended dose is 6 tablets (3000 mg) per day.

Overdose:

If you think you, or a person you are caring for, have taken too much Velphoro, contact a healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

- If you miss a dose of Velphoro, skip that dose and take your next dose at your usual time.
- Do not take double your dose at a meal to make up for a missed dose.

What are possible side effects from using Velphoro?

These are not all the possible side effects you may feel when taking Velphoro. If you experience any side effects not listed here, tell your healthcare professional.

Very common (more than 1 in 10 people):

- black stools
- diarrhea (generally occurring early on in the treatment and improving over time)

Common (up to 1 in 10 people):

- feeling sick (nausea)
- constipation
- vomiting
- indigestion
- pain in stomach and intestines
- gas

Uncommon (up to 1 in 100 people):

- bloating (abdominal distension)
- inflammation of the stomach
- abdominal discomfort
- difficulty swallowing
- acid coming back up from the stomach (gastro-esophageal reflux disease)
- tongue discoloration
- stained teeth
- low or high calcium levels in the blood seen in tests
- tiredness
- itch, rash
- headache
- shortness of breath

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON Abdominal pain		√	
RARE Bowel obstruction and/or lesions: abdominal discomfort, abdominal swelling, cramping, difficulty passing stools, constipation, nausea/vomiting especially after meals, excessive burping, black stools	√		
Allergic reactions: rash, swelling of the face or mouth, difficulty breathing	√		
Dysphagia: Difficulty swallowing problems with your esophagus	√		

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

<p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or • Calling toll-free at 1-866-234-2345. <p><i>NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.</i></p>
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Storage:

- Store Velporo at room temperature (15 to 30°C).
- Store it in the original package and keep the bottle tightly closed to protect from moisture.
- After opening the bottle, the chewable tablets can be used for 90 days.
- Do not use this medicine after the expiry date stated on the carton or bottle after “EXP”. The expiry date refers to the last day of the month.
- Do not throw away any medicines via wastewater or household waste. Ask your healthcare professional how to throw away medicines you no longer use. These measures will help protect the environment.

Keep out of reach and sight of children.

If you want more information about Velphoro:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); or by calling 1-877-341-9245.

This leaflet was prepared by Vifor Fresenius Medical Care Renal Pharma Ltd.

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