

Velphoro Chewable Tablet 500mg

Iron (as sucroferic oxyhydroxide) 500mg

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1.What Velphoro is used for

Velphoro is a medicine that contains the active substance sucroferic oxyhydroxide, which is made up from iron, sugar (sucrose) and starches.

Velphoro is for use by adult patients who undergo haemodialysis or peritoneal dialysis (procedures to eliminate toxic substances from the blood) because of chronic kidney disease; it is used in order to help control the phosphorus level in their blood when it is too high (hyperphosphataemia).

2.How Velphoro works

Too much phosphorus in the blood can lead to calcium being deposited in tissues (calcification). This can result in stiffening of the blood vessels, making it harder for the blood to be pumped around the body. It may also lead to calcium deposits in soft tissues and bone causing effects such as red eyes, itchy skin and bone pain.

Velphoro works by binding phosphorus from food in your digestive tract (stomach and intestines). This reduces the amount of phosphorus that can be absorbed into the

bloodstream and thus lowers phosphorus levels in your blood.

3.Before you use Velphoro

When you must not use it:

- if you are allergic to sucroferic oxyhydroxide or any of the other ingredients of this medicine (listed in section 8)
- if you have a history of abnormal iron build-up in your organs (haemochromatosis)
- if you have any other disorder associated with too much iron.

If you are not sure, talk to your doctor before taking this medicine.

Before you start to use it

Talk to your doctor or pharmacist before taking Velphoro:

- if you have had peritonitis, an inflammation of the peritoneum (the thin tissue that lines the inner wall of the abdomen) within the last 3 months,
- if you have significant stomach and/or liver problems,
- if you have had major surgery on your stomach and/or intestines.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking this medicine.

Velphoro can cause black stools. Any potential bleeding from your digestive tract (stomach and gut) may be hidden by these black stools. **If you have black stools and also have symptoms like increasing tiredness and breathlessness contact your**

doctor immediately (see section 6).

Children and adolescents

The safety and efficacy of Velphoro in children and adolescents below the age of 18 years has not yet been established. Therefore Velphoro is not recommended for use in children and adolescents.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you are taking any other medicine that is known to be affected by iron (for example medicines containing the active substance alendronate (used to treat certain bone disorders) or doxycycline (an antibiotic)) or has the potential to be affected by iron (for example medicines containing the active substance levothyroxine (used to treat thyroid function disorder)), make sure that you take this medicine at least one hour before taking Velphoro or at least two hours after taking Velphoro. Ask your doctor if you are not sure.

Pregnancy and breastfeeding

There is no information on the effects of this medicine if taken during pregnancy or breastfeeding. If you are pregnant or breastfeeding, or you think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Your doctor will advise you whether Velphoro should be used during pregnancy, based on benefit and risk assessment for use during pregnancy.

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If you are breastfeeding, your doctor will discuss with you whether to continue breastfeeding or to continue therapy with Velphoro, taking into account the benefit of Velphoro therapy to you and the benefit of breastfeeding to your child.

It is unlikely that this medicine would pass into the mother's milk.

Driving and using machines

This medicine has no significant effect on your ability to drive or to use tools or machines.

Velphoro contains sucrose and starches (carbohydrates)

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Velphoro may be harmful to the teeth.

Velphoro contains starches. If you have diabetes you should take notice that one tablet of Velphoro is equivalent to approximately 1.4 g of carbohydrates (equivalent to 0.116 bread units).

4. How to use Velphoro

How much to use, when to use and how long to use it

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual recommended starting dose is the equivalent of 1,500 mg iron per day (3 tablets).

The maximum recommended dose is 3,000 mg iron (6 tablets) per day.

Your doctor may adjust the dose during the treatment course depending on the phosphorus level in your blood.

Method of administration

- Velphoro should only be taken by mouth.
- Take the tablet during a meal and chew it (if necessary, the tablet may be crushed to make this easier for you). DO NOT swallow it whole.
- The amount of tablets taken per day should be divided across the meals of the day.
- When taking Velphoro you should adhere to your recommended diet and treatments prescribed by your doctor such as calcium supplements, vitamin D3 or calcimimetics.

If you forget to use it

If you have missed a dose, just take the next dose at the usual time with a meal. Do not take a double dose to make up for a forgotten dose.

If you use too much (overdose)

If you have accidentally taken too many tablets, do not take any more and talk to your doctor or pharmacist immediately.

5. While you are using it

Things you must do

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by

visiting the website npra.gov.my [Consumers->Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Things you must not do

Do not stop taking the medicine before talking to your doctor or pharmacist as the phosphorus level in your blood may increase (see section 1).

Things to be careful of

Velphoro can cause black stools. Any potential bleeding from your digestive tract (stomach and gut) may be hidden by these black stools. **If you have black stools and also have symptoms like increasing tiredness and breathlessness contact your doctor immediately** (see section 6).

6. Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Black stools may occur very commonly in patients taking Velphoro. If you also have symptoms like increasing tiredness and breathlessness contact your doctor immediately (see section 3).

The following side effects have also been reported in patients taking this medicine:

Very common (may affect more than 1 in 10 people): diarrhoea (generally occurring early on in the treatment, and improving over time).

Common (may affect up to 1 in 10 people): feeling sick (nausea), constipation, vomiting, indigestion, pain in stomach and gut, gas, tooth discolouration, change in taste.

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Uncommon (may affect 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-oesophageal reflux disease), tongue discolouration, low or high calcium levels in the blood seen in tests, tiredness, itch, rash, headache, shortness of breath.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers->Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

7.Storage and Disposal of Velphoro

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the carton, bottle or blister after "EXP". The expiry date refers to the last day of that month.

After first opening of the bottle the chewable tablets can be used for 45 days.

Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

8.Product Description

What it looks like

The chewable tablets are brown, circular, and embossed with PA500 on one side. The tablets have a 20 mm diameter and a thickness of 6.5 mm.

The tablets are packed in high density polyethylene bottles with a child resistant polypropylene closure and a foil induction seal.

Not all pack sizes may be marketed.

Ingredients

-The active substance is sucroferic oxyhydroxide which is comprised of polynuclear iron(III) oxyhydroxide, sucrose, and starches. Each chewable tablet contains sucroferic oxyhydroxide corresponding to 500 mg iron. Each tablet also contains 750

mg sucrose and 700 mg starches. See section 3 for further information on sucrose and starches.

-The other ingredients are woodberry flavour, neohesperidin, dihydrochalcon, magnesium stearate, colloidal anhydrous silica.

MALNUMBER:
MAL22016004ARZ

9.Manufacturer and Product Registration Holder

Manufacturer

Corden Pharma Fribourg SA
Route de Moncor
CH-1752 Villars-sur-Glâne
Switzerland

Product Registration Holder/Importer

Fresenius Kabi Malaysia Sdn. Bhd
3-1&3-2, Axis Technology Centre
Jalan 51A / 225, 46100 Petaling Jaya
Selangor, Malaysia

10.Date of Revision :
23/08/2023

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