

Package leaflet: Information for the patient

Velphoro 500 mg chewable tablets iron as sucroferric oxyhydroxide

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Velphoro is and what it is used for
2. What you need to know before you take Velphoro
3. How to take Velphoro
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1. What Velphoro is and what it is used for

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

This medicine is used to control high blood phosphate levels (hyperphosphataemia) in:

- adult patients who undergo haemodialysis or peritoneal dialysis (procedures to eliminate toxic substances from the blood) because of chronic kidney disease;
- children from 2 years of age and adolescents with chronic kidney disease stages 4 and 5 (severe decrease in the ability of the kidneys to work properly) or on dialysis.

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.

This medicine 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.

2. What you need to know before you take Velphoro

Do not take Velphoro

- if you are allergic to sucroferric oxyhydroxide or any of the other ingredients of this medicine (listed in section 6);
- 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.

Warnings and precautions

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.

This medicine 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 4).

Children and adolescents

The safety and efficacy in children below the age of 2 years has not yet been established. Therefore, this medicine is not recommended for use in children under 2 years.

Other medicines and Velphoro

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 breast-feeding

There is no information on the effects of this medicine if taken during pregnancy or breast-feeding. If you are pregnant or breast-feeding, 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.

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

This medicine may be harmful to the teeth.

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

3. How to take Velphoro

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:

- in children 6 to less than 9 years is 750 mg iron per day *
- in children and adolescents 9 to 12 years is 1,000 mg iron (2 tablets) a day,
- for adults and adolescents above 12 years of age is 1,500 mg iron per day (3 tablets).

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

The maximum recommended dose:

- in children 6 to less than 9 years is 2,500 mg iron (5 tablets) per day,
- in children and adolescents 9 to 18 years and adults is 3,000 mg iron (6 tablets) per day.

* Velphoro is also available as oral powder in sachet (equivalent to 125 mg iron) for use in children 2 to less than 12 years.

Method of administration

- Take this medicine only 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.
- Divide the amount of tablets taken per day 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 (used to treat problems with parathyroid glands).

Only for the blister packs:

- Separate the blister pack at perforations.
- Peel back the paper foil at the corner.
- Push the tablet through the aluminium foil.

If you take more Velphoro than you should

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

If you forget to take Velphoro

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 stop taking Velphoro

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).

4. Possible 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 2 “Warnings and precautions”).

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.

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.

Reporting of side effects

Reporting of side effects If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Velphoro

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

Do not use this medicine after the expiry date which is 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 90 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.

6. Contents of the pack and other information

What Velphoro contains

- The active substance is sucroferric oxyhydroxide which is comprised of polynuclear iron(III)-oxyhydroxide, sucrose, and starches. Each chewable tablet contains sucroferric oxyhydroxide corresponding to 500 mg iron. Each tablet also contains 750 mg sucrose and 700 mg starches. See section 2 for further information on sucrose and starches.
- The other ingredients are woodberry flavour, neohesperidin-dihydrochalcone, magnesium stearate, colloidal anhydrous silica.

What Velphoro looks like and contents of the pack

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, or in child resistant aluminium blister.

Velphoro is available in packs containing 30 or 90 chewable tablets. Multipacks are available for the blister packs with 90 chewable tablets (containing 3 individual packs of 30 × 1 chewable tablets each).

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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For any information about this medicine, please contact the Marketing Authorisation Holder.

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