

## Package leaflet: Information for the patient

### Velphoro 125 mg oral powder in sachet 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
4. Possible side effects
5. How to store Velphoro
6. Contents of the pack and other information

#### **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 sachet of Velphoro powder is equivalent to approximately 0.7 g of carbohydrates (equivalent to 0.056 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.

For children 2 years and above, the doctor will decide the right dose based on the age of the child. The starting dose of Velphoro oral powder is taken three times daily with food as shown below:

Child age	Recommended daily starting dose
2 to less than 6 years	500 mg iron (4 sachets)
6 to less than 9 years	750 mg iron (6 sachets)
9 to less than 12 years	1,000 mg iron (2 tablets or 8 sachets)

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

Velphoro is also available as chewable tablets for use in children and adolescents 6 to 18 years and in adults.

The maximum recommended dose:

- in children 2 to less than 6 years is 1,250 mg iron (10 sachets) per day,
- 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 is 3,000 mg iron (6 tablets) per day.

#### Method of administration

- Take this medicine only during meal.
  - Mix Velphoro oral powder with:
    - small amount of soft food, such as apple sauce, or
    - small amount of non-carbonated beverage or water
- The powder will not dissolve completely and will remain in suspension with a red-brown colour.
- Drink powder suspension within 30 minutes after being prepared.
  - Mix the powder again, if necessary, right before drinking.
  - Do not heat Velphoro oral powder (such as in a microwave) and do not add it to heated food or liquids.
  - When taking Velphoro you should adhere to your recommended diet and treatments prescribed by your doctor such as calcium supplements, vitamin D<sub>3</sub> or calcimimetics (used to treat problems with parathyroid glands).

#### If you take more Velphoro than you should

If you have accidentally taken too many sachets of oral powder, 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

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](http://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 or sachet after “EXP”. The expiry date refers to the last day of that month.

Take the reconstituted suspension within 30 minutes of reconstitution.  
This medicine does not require any special storage conditions.

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 sachet contains sucroferric oxyhydroxide corresponding to 125 mg iron. Each sachet also contains 187 mg sucrose and 175 mg starches. See section 2 for further information on sucrose and starches.
- The other ingredients are maltodextrin, microcrystalline cellulose, xanthan gum, magnesium stearate, colloidal anhydrous silica.

**What Velphoro looks like and contents of the pack**

Velphoro oral powder is red-brown, packed in child resistant twin single-dose sachets.

Velphoro oral powder is available in packs containing 90 sachets.

**Marketing Authorisation Holder**

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

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