

VELPHORO® 500 mg chewable tablets

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using VELPHORO?

VELPHORO contains 2500 mg of the active substance sucroferric oxyhydroxide which corresponds to 500 mg iron. VELPHORO is used to control the phosphorus levels in the blood of patients with chronic kidney disease (CKD) on dialysis.

For more information, see Section [1. Why am I using VELPHORO?](#) in the full CMI.

2. What should I know before I use VELPHORO?

Do not use if you have ever had an allergic reaction to active substance sucroferric oxyhydroxide or any of the ingredients listed at the end of the CMI. Do not use if you have too much iron or any other problems with the iron levels in your body.

Talk to your doctor or pharmacist if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use VELPHORO?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with VELPHORO and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use VELPHORO?

- Use as directed by your doctor. Check with your doctor or pharmacist if you are not sure
- Take the tablet during a meal and chew it. DO NOT swallow it whole.

More instructions can be found in Section [4. How do I use VELPHORO?](#) in the full CMI.

5. What should I know while using VELPHORO?

Things you should do	<ul style="list-style-type: none">• If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using VELPHORO.• Keep all of your doctor's appointments so that your progress can be checked.• If you become pregnant while taking this medicine, tell your doctor immediately.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine or lower the dosage without checking with your doctor or pharmacist.• Do not use VELPHORO to treat any other complaints unless your doctor tells you to.• Do not give your medicine to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how VELPHORO affects you.
Looking after your medicine	<ul style="list-style-type: none">• Store below 30°C.• Store it in a cool dry place away from moisture, heat or sunlight• Store in the original container.• Keep this medicine out of the sight and reach of young children.

For more information, see Section [5. What should I know while using VELPHORO?](#) in the full CMI.

6. Are there any side effects?

The most common side effects are diarrhoea, discoloured faeces, nausea, constipation, vomiting, indigestion, abdominal pain, flatulence, and discolouration of teeth and/or tongue. Serious side effects include fatigue and breathlessness.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

VELPHORO® 500 mg chewable tablets

Active ingredient(s): Each chewable tablet contains 500 mg iron (equivalent to 2500 mg sucroferri oxyhydroxide)

Consumer Medicine Information (CMI)

This leaflet provides important information about using VELPHORO. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using VELPHORO.**

Where to find information in this leaflet:

- [1. Why am I using VELPHORO?](#)
- [2. What should I know before I use VELPHORO?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use VELPHORO?](#)
- [5. What should I know while using VELPHORO?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using VELPHORO?

VELPHORO contains 2500 mg of the active substance sucroferri oxyhydroxide which corresponds to 500 mg iron. VELPHORO belongs to a group of drugs used when the levels of phosphorus in blood are too high (a condition called hyperphosphataemia).

VELPHORO is used to control the phosphorus levels in the blood of patients with chronic kidney disease (CKD) on dialysis. The active ingredient works by binding phosphate from food in the digestive tract. This reduces how much is absorbed and the levels of phosphorus in the blood.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

2. What should I know before I use VELPHORO?

Warnings

Do not use VELPHORO if:

- you are allergic to the active substance sucroferri oxyhydroxide, or to any of the other ingredient(s) listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you are allergic to any other similar medicines

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine if you have too much iron in your body (haemochromatosis) or any other problems with the iron levels in your body.

Check with your doctor or pharmacist if you:

- have any other medical conditions
- have allergies to any other medicines, foods, preservatives or dyes
- take any medicines for any other condition
- have inflammation of the thin tissue (serous membrane) that lines the inner wall of the abdomen (peritonitis)
- have significant stomach and/or liver disorders
- have had major surgery on your stomach and/or intestines
- have a history of abnormal iron accumulation in your bodily organs (haemochromatosis) or other iron disorders
- have an intolerance to some sugars

Do not take this medicine if you have too much iron in your body (haemochromatosis) or any other problems with the iron levels in your body.

If you are not sure whether you should start taking this medicine, talk to your doctor. During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

If you become pregnant while taking this medicine, tell your doctor immediately.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins, or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with VELPHORO and affect how it works. These include:

- alendronate (a medicine used to treat or prevent osteoporosis)
- doxycycline (antibiotics to treat infections)
- levothyroxine (a medicine used to treat thyroid problems)

These medicines may be affected by VELPHORO or may affect how well it works. You may need different amounts of your medicines. It is recommended that these drugs should be administered at least 1 hour before or at least 2 hours after intake of VELPHORO.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect VELPHORO.

4. How do I use VELPHORO?

How much to take

- The standard dose for this medicine is one tablet three times a day.
- The usual recommended starting dose is 1,500 mg iron per day (1 tablet, 3 times a day).
- The maximum recommended dose is 3,000 mg iron (2 tablets, 3 times a day).

Your doctor may have prescribed a different dose.

Follow the instructions provided and use VELPHORO until your doctor or pharmacist tells you to stop. Your doctor may adjust the dose during the treatment course depending on the phosphorus level in your blood.

If you take the wrong dose, VELPHORO may not work as well, and your problem may not improve.

If you do not understand the instructions, ask your doctor or pharmacist for help. Ask your doctor or pharmacist if you are unsure of the correct dose for you.

When to take VELPHORO

Take your medicine during or immediately after a meal, at about the same time each day. Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

If you take it on an empty stomach, it may cause stomach upset.

The amount of tablets taken per day should be divided across the three largest meals of the day.

How to take VELPHORO

VELPHORO chewable tablets should only be taken by mouth.

Take the tablet during a meal and chew it. DO NOT swallow it whole.

If necessary, the tablet may be crushed to make this easier for you.

No additional fluid above the amount usually taken due to your kidney disease is required.

Additional information for the blister pack:

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

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take VELPHORO

VELPHORO should be used regularly at the same time each day to have the best effect.

If you miss your dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed. This may increase the chance of you getting an unwanted side effect.

If you use too much VELPHORO

If you think that you have used too much VELPHORO, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor or pharmacist, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using VELPHORO?

Things you should do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking VELPHORO.

Tell any doctor or pharmacist, dentist, or pharmacist you visit that you are using VELPHORO.

Keep all of your doctor's appointments so that your progress can be checked

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

If you become pregnant while taking this medicine, tell your doctor immediately.

Things you should not do

- Do not stop using this medicine suddenly or lower your dose without checking with your doctor or pharmacist. If you stop taking it suddenly, your condition may worsen.
- Do not take this medicine to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how VELPHORO affects you.

It is unlikely that this medicine will affect your ability to drive or to operate tools or machines. Ask your doctor if you are not sure.

Looking after your medicine

- Store below 30°C
- **Store in the original container**

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight, for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

When to discard your medicine

Do not take this medicine after the expiry date printed on the pack or 90 days after opening (whichever is earlier) or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Getting rid of any unwanted medicine

If your doctor tells you to stop taking this medicine or the expiry date has passed, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Gastrointestinal related:</p> <ul style="list-style-type: none">• Abdominal pain• Diarrhoea• Constipation• Discoloured faeces* <p>*As is often seen with oral iron preparations, discoloured (black) stools may occur very commonly in patients taking VELPHORO®. This may visually hide gastrointestinal bleeding. If you also have symptoms like increasing fatigue and breathlessness, contact your doctor immediately.</p> <ul style="list-style-type: none">• Flatulence• Indigestion• Nausea• Vomiting• Abdominal distension (bloating)• Abdominal discomfort• Gastritis• Gastro-oesophageal reflux disorder (GORD) <p>Head related:</p> <ul style="list-style-type: none">• Fatigue• Headache <p>Other:</p> <ul style="list-style-type: none">• Discolouration of teeth and/or tongue	<p>Speak to your doctor or pharmacist if you have any of these side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Gastrointestinal related:</p> <ul style="list-style-type: none">• Difficulty swallowing <p>Skin related:</p> <ul style="list-style-type: none">• Itching skin• Rash <p>Respiratory related:</p> <ul style="list-style-type: none">• Shortness of breath <p>Blood related:</p> <ul style="list-style-type: none">• Too high or too low levels of calcium in your blood	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist or pharmacist if you notice anything else that may be making you feel unwell.

This includes any other possible side effects not listed here that may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor or pharmacist's prescription.

What VELPHORO contains

Active ingredient (main ingredient)	2500 mg sucroferric oxyhydroxide (equivalent to 500 mg iron). The active ingredient sucroferric oxyhydroxide contains 750 mg sucrose and 700 mg starches.
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• woodberry flavour• neohesperidin dihydrochalcone• magnesium stearate• silica (colloidal, anhydrous)

Do not take this medicine if you are allergic to any of these ingredients.

What VELPHORO looks like

VELPHORO chewable tablets are brown, circular, bi-planar tablets embossed with PA500 on one side.

The tablets are packed in high density polyethylene bottles with a child resistant polypropylene cap and a foil induction seal, or in child resistant aluminium blister packs.

VELPHORO is available in packs containing 30 or 90 chewable tablets.

Australian Registration Numbers:

AUST R 216701 (blister pack)

AUST R 216702 (bottle pack)

Who distributes VELPHORO

Distributed in Australia by:

CSL Seqirus

655 Elizabeth Street,

Melbourne, VIC 3000

Australia

1800 642 865 (Within Australia)

Sponsor

Seqirus Pty Ltd

63 Poplar Rd,

Parkville VIC 3052

Australia

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