

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 VENOFER?

VENOFER provides a source of iron that can help to replenish a shortage of iron in patients with iron deficiency. For more information, see Section [1. Why am I using VENOFER?](#) in the full CMI.

2. What should I know before I use VENOFER?

Do not use if you have ever had an allergic reaction to VENOFER or any of the ingredients listed at the end of the CMI.

Talk to your doctor 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 VENOFER?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines, such as iron tablets and VENOFER may interfere with each other. 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 VENOFER?

Your doctor or nurse will prepare this medicine for you. VENOFER is a sterile solution which is diluted immediately before use. It is given by intravenous infusion or by slow injection into the venous limb of the dialysis line for haemodialysis patients. More instructions can be found in Section [4. How do I use VENOFER?](#) in the full CMI.

5. What should I know while using VENOFER?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using VENOFER.
Things you should not do	<ul style="list-style-type: none">Do not take VENOFER if your anaemia is not due to shortage of iron.Do not take VENOFER if you are in the first trimester of pregnancy.Do not take VENOFER if you have a condition known as haemo-chromatosis (an excess of iron in the body) or a genetic tendency towards this condition.
Driving or using machines	Be careful before you drive or use any machines or tools until you know how VENOFER affects you.
Drinking alcohol	Tell your doctor if you drink alcohol.
Looking after your medicine	Normally, your doctor will get VENOFER from the hospital pharmacy or their consulting rooms. However, if for any reason you take this medicine from the pharmacy to your doctor, it is important to store it in a safe place, away from heat and light, where the temperature stays below 25°C.

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

6. Are there any side effects?

The common side effects include dizziness, temporary change in taste, injection site reactions (such as pain, irritation, discolouration, burning, swelling or bruising). Serious side effects include rapid, shallow breathing, cold and clammy skin, chest pain, weakness and fainting, weak rapid pulse, convulsions, facial swelling and difficulty in breathing.

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.

VENOFER®

Active ingredient: *iron sucrose*

Consumer Medicine Information (CMI)

This leaflet provides important information about using VENOFER. **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 VENOFER.**

Where to find information in this leaflet:

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

1. Why am I using VENOFER?

VENOFER contains the active ingredient iron sucrose.

VENOFER provides a source of iron that can help to replenish a shortage of iron in patients with iron deficiency. **Ask your doctor if you have any questions about why VENOFER has been prescribed for you.**

This medicine is only available with a doctor's prescription. There is no evidence that it is addictive.

2. What should I know before I use VENOFER?

Warnings

Do not use VENOFER if:

- you are allergic to iron sucrose or any of the ingredients listed at the end of this leaflet.
- your anaemia is not due to a shortage of iron
- you are in the first trimester of a pregnancy
- you have a condition known as haemo-chromatosis (an excess of iron in the body) or a genetic tendency towards this condition.

Check with your doctor if you:

- or a blood relative have the condition known as haemochromatosis
- have an infection
- have liver disease

You should be aware that:

- a blood test should have been carried out to ensure treatment with this medicine is appropriate

- if you have a history of asthma, eczema or other atopic allergies you are more susceptible to experience allergic reactions
- intravenous iron preparations can cause severe allergic reactions. These allergic reactions may include chest pain. **Tell your doctor immediately if you experience it.**

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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 if you are pregnant or intend to become pregnant.

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

You should be aware that:

- slow heartbeat may occur in unborn babies whose mothers have been administered intravenous iron due to allergic reactions in the mother.

Use in children

The safety and efficacy of VENOFER in children has not been established.

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, such as iron tablets and VENOFER may interfere with each other.

These medicines may be affected by VENOFER or may affect how well it works. You may need to take different amounts of your medicine or you may need to take different medicines.

Your doctor has more information on medicines to be careful with or avoid while being given this medicine.

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

4. How do I use VENOFER?

How much to take

Your doctor will decide what dose and for how long you will receive VENOFER. This depends on your response to the treatment. Your doctor may change the dose and frequency of your medicine as your condition changes.

How to take

- Your doctor or nurse will prepare this medicine for you.
- VENOFER is a sterile solution which is diluted immediately before use. It is given by intravenous infusion or by slow injection into the venous limb of the dialysis line for haemodialysis patients.
- It must not be given by intramuscular or subcutaneous injection.

If you are given too much VENOFER

As VENOFER is given to you under the supervision of your doctor, it is very unlikely that you will be given an overdose.

If you think that you have been given too much, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, nurse, 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 VENOFER?

Things you must do

- Your doctor may order regular blood tests while you are receiving VENOFER in order to monitor your iron levels.

Call your doctor straight away:

- If you experience any side effects after being given VENOFER

Remind any doctor, dentist or pharmacist you visit that you are using VENOFER as it may interact with other medicines or anaesthetics they may use.

Driving or using machines

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Normally, your doctor will get VENOFER from the hospital pharmacy or their consulting rooms. However, if for any reason you take this medicine from the pharmacy to your doctor, it is important to store it in a safe place, away from heat and light, where the temperature stays below 25°C.
- The product should not be frozen.
- Once the ampoules have been opened, they should be used immediately.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

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.

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
Head related <ul style="list-style-type: none">• dizziness• lightheadedness• fatigue• fever, shivering• temporary change in taste (e.g. metallic taste) Stomach related <ul style="list-style-type: none">• nausea General disorders <ul style="list-style-type: none">• injection site reactions (such as pain, irritation, discolouration, burning, swelling or bruising)• fever, shivering	Speak to your doctor, nurse, or pharmacist if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Head related <ul style="list-style-type: none">headacheanxietypallor Muscle and joint related <ul style="list-style-type: none">muscle pain, crampsjoint pain Breathing related <ul style="list-style-type: none">rapid, shallow breathingdifficulty in breathing Heart related <ul style="list-style-type: none">irregular heart beat Stomach related <ul style="list-style-type: none">stomach paindiarrhoeavomitingconstipation Skin related <ul style="list-style-type: none">tingling or prickling sensation or numbnessitchy skin and rashburning sensationincreased sweating Bleeding related <ul style="list-style-type: none">easy bruising or bleeding Urine related <ul style="list-style-type: none">abnormal urine colour	Tell your doctor or nurse immediately if you notice any of the these side effects
Skin related <ul style="list-style-type: none">cold, clammy skin Head related <ul style="list-style-type: none">dizziness, weakness and faintingunusual weakness or tirednessconvulsionsfacial swelling Heart related <ul style="list-style-type: none">chest painweak rapid pulse	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.

Tell your doctor, nurse, or pharmacist if you notice anything else that may be making you feel unwell while you are being given VENOFER, even if you think the problems are not connected with this medicine and are not referred to in this leaflet.

Other side effects not listed here 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 before you decide to stop taking any of your medicines.

7. Product details

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

What VENOFER contains

Active ingredient (main ingredient)	Each 5 mL ampoule contains 100 mg of iron as iron sucrose (iron (III)-hydroxide sucrose complex)
Other ingredients (inactive ingredients)	sodium hydroxide water for injections
Potential allergens	NA

Venofer does not contain lactose, sucrose, gluten, tartrazine or any azo dyes.

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

What VENOFER looks like

VENOFER is a sterile dark brown, non-transparent aqueous solution contained in a 5 mL glass ampoule. Available in packs of 5 ampoules.

Australian registration number: AUST R 98236

Who distributes VENOFER

VENOFER is supplied in Australia by:

Vifor Pharma Pty Ltd
655 Elizabeth Street
Melbourne VIC 3000
Australia
Ph: 1800 202 674

New Zealand distributor:
Pharmacy Retailing (NZ) Limited
trading as Healthcare Logistics
Auckland, New Zealand

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