
Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about VENOFER.

It does not contain all the available information. It does not take the place of talking to your doctor.

All medicines have risks and benefits.

Your doctor has weighed the risks of you being given VENOFER against the benefits they expect it will have for you.

If you have any concerns about receiving VENOFER ask your doctor.

Keep this leaflet with the medicine.
You may need to read it again.

What VENOFER is used for

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.

Your doctor may have prescribed it for another reason.

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

There is no evidence that it is addictive.

Before you are given VENOFER

When you must not be given it

You must not be given VENOFER if:

- you are known to be sensitive to any of the ingredients of this medicine 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 haemochromatosis (an excess of iron in the body) or a genetic tendency towards this condition.

VENOFER should not be used after the expiry date printed on the label.

If you are not sure whether you should be given VENOFER, talk to your doctor.

Before you are given it

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.

Tell your doctor if you have or have had any of the following medical conditions:

- you or a blood relative have the condition known as haemochromatosis
- if you have an infection

- liver disease.

Tell your doctor if you are pregnant or plan to become pregnant or are breast feeding.

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.

If you have not told your doctor about any of the above, tell them before you are given VENOFER.

Use in children

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

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your supermarket, pharmacy 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.

How VENOFER is given

How much is given

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

How it is given

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.

Your doctor or nurse will prepare this medicine for you.

What to expect

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

If you are given too much (overdose)

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

However, if you experience any side effects after being given VENOFER, tell your doctor or nurse immediately.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being given VENOFER.

All medicines can have side effects. Sometimes they are serious, most of the time

they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor to answer any questions you may have.

Tell your doctor or nurse if you notice any of the following and they worry you:

- temporary change in taste (e.g. metallic taste)
- dizziness, lightheadedness
- fever, shivering
- injection site reactions (such as pain, irritation, discolouration, burning, swelling or bruising)
- nausea
- fatigue

The above list includes the more common side effects of your medicine.

Tell your doctor or nurse immediately if you notice any of the following:

- stomach pain, diarrhoea, vomiting
- constipation
- headache or migraine
- muscle pain, cramps
- irregular heart beat
- itchy skin and rash
- unusual weakness or tiredness
- burning sensation
- tingling or prickling sensation or numbness
- anxiety
- increased sweating
- easy bruising or bleeding
- abnormal urine colour
- dry mouth
- joint pain
- pallor

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following symptoms:

- rapid, shallow breathing
- cold, clammy skin
- weak, rapid pulse
- chest pain
- dizziness, weakness and fainting
- convulsions
- facial swelling
- difficulty in breathing.

These rare side effects are symptoms of a severe allergic reaction. You may need urgent medical attention.

Tell your doctor if you notice anything else that is making you feel unwell, 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 above may also occur in some people.

Do not be alarmed by this list of side effects.

You may not experience any of them.

After using VENOFER

Storage

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.

Product description

What it looks like

VENOFER is a sterile dark brown, nontransparent aqueous solution contained in a 5 mL glass ampoule.

Available in packs of 5 ampoules.

Ingredients

Active ingredient:

Each 5 mL ampoule contains 100 mg of iron as iron sucrose (iron (III)-hydroxide sucrose complex).

Inactive ingredients:

- sodium hydroxide
- water for injections.

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

Sponsor

VENOFER is supplied in Australia by:

Vifor Pharma Pty Ltd
Level 9, 140 William Street
Melbourne VIC 3000
Australia

Exclusive New Zealand distributor:

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

Australian registration number:
AUST R 98236

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