Package leaflet: Information for the user
Venofer 20 mg iron /mL
Solution for injection or concentrate for solution for infusion
Iron Sucrose

Read all of this leaflet carefully before you are given 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.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Venofer is and what it is used for

Venofer is a medicine that contains iron.

Medicines that contain iron are used when you do not have enough iron in your body. This is called “iron deficiency”.

Venofer is given when:
- You cannot take iron by mouth - such as when iron tablets make you feel ill.
- You have taken iron by mouth - and it has not worked.

2. What you need to know before Venofer is given to you

You must not receive Venofer if:

- You are allergic (hypersensitive) to the product or any of the other ingredients of this medicine (listed in section 6).
- You have experienced serious allergic (hypersensitive) reactions to other injectable iron preparations.
- You have anaemia which is not caused by a shortage of iron.
- You have too much iron in your body or a problem in the way your body uses iron.

You must not be given Venofer if any of the above apply to you. If you are not sure, talk to your doctor before having Venofer.

Warnings and precautions

Talk to your doctor or nurse before receiving Venofer if:

- You have a history of medicine allergy.
- You have systemic lupus erythematosus.
- You have rheumatoid arthritis.
- You have severe asthma, eczema or other allergies.
- You have any infections.
- You have liver problems.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before you are given Venofer.

Other medicines and Venofer

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines.

This is because Venofer can affect the way some other medicines work. Also some other medicines can affect the way Venofer works.

In particular tell your doctor or pharmacist if you are taking:
- Medicines that contain iron which you take by mouth. These may not work if they are taken at the same time that Venofer is given to you.

Pregnancy and breast-feeding

Venofer has not been tested in women who are in the first three months of their pregnancy. It is important to tell your doctor if you are pregnant, think you may be pregnant, or are planning to have a baby.
If you become pregnant during treatment, you must ask your doctor for advice.
Your doctor will decide whether or not you should be given this medicine.

If you are breast-feeding, ask your doctor for advice before you are given Venofer.

Ask your doctor or pharmacist for advice before taking any medicine, if you are pregnant or breast-feeding.

Driving and using machines

You may feel dizzy, confused or light-headed after being given Venofer. If this happens, do not drive or use any tool or machines. Ask your doctor if you are not sure.

Venofer contains Sodium

Venofer contains up to 7 mg sodium (main component of cooking/table salt) per mL. This is equivalent to 0.4% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Venofer is given

Your doctor will decide how much Venofer to give you. He or she will also decide how often you need it and for how long. Your doctor will do a blood test to help work out the dose.

Your doctor or nurse will administer Venofer in one of the following ways:
- Slow injection into your vein – 1 to 3 times per week.
- As an infusion (drip) into your vein – 1 to 3 times per week.
- During dialysis – it will be put into the venous line of the dialysis machine.

Venofer will be administered in a structure where immunoallergic events can receive appropriate and prompt treatment.
You will be observed for at least 30 minutes by your doctor or nurse after each administration.

Venofer is a brown liquid and so the injection or infusion will look brown.

Use in children

Venofer is not recommended for use in children.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Allergic reactions (uncommon)
If you have an allergic reaction, tell your doctor or nurse straight away. The signs may include:
- Low blood pressure (feeling dizzy, light-headed or faint).
- Swelling of your face.
- Difficulty breathing.
- Chest pain which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

In some patients these allergic reactions (rare) may become severe or life-threatening (known as anaphylactoid/anaphylactic reactions).
Tell your doctor or nurse straight away if you think you are having an allergic reaction.

Other side effects include:

Common (may affect up to 1 in 10 people)
- Changes in your taste such as a metallic taste. This does not usually last very long.
- Low blood pressure or high blood pressure.
- Feeling sick (nausea).
- Reactions around the site of injection/ infusion such as pain, irritation, itching, haematoma or discolouration following the leakage of the injection into the skin.

Uncommon (may affect up to 1 in 100 people)
- Headache or feeling dizzy.
- Stomach pain or diarrhoea.
- Being sick (vomiting).
- Wheezing, difficulty in breathing.
- Itching, rash.

- Muscle spasms, cramps or pain.
- Tingling or “pins and needles”.
- Reduced sensation of touch.
- Vein inflammation.
- Flushing burning sensation.
- Constipation.
- Joint pain.
- Pain in limbs.
- Back pain.
- Chills.
- Weakness, tiredness.
- Swelling of hands and feet.
- Pain.
- Increased levels of liver enzymes (ALT, AST, GGT) in the blood.
- Increased serum ferritin levels.

Rare (may affect up to 1 in 1,000 people)
- Fainting.
- Sleepiness or drowsiness.
- Pounding heart beat (palpitations).
- Changes to the colour of your urine.
- Chest pain.
- Increased sweating.
- Fever.
- Increased lactate dehydrogenase in the blood.

Other side effects with unknown frequency include: feeling less alert, feeling confused; loss of consciousness; anxiety; trembling or shaking; swelling of your face, mouth, tongue or throat which may cause difficulty in breathing; low pulse rate; fast pulse rate; circulatory collapse; vein inflammation causing the formation of a blood clot; acute narrowing of the airways; itching, hives, rash or skin redness; cold sweat; general feeling of illness; pale skin; sudden life-threatening allergic reactions. Flu-like illness may occur a few hours to several days after injection and is typically characterised by symptoms such as high temperature, and aches and pains in muscles and joints.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

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

5. How to store Venofer

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 label after EXP.
Do not store above 25°C. Do not freeze. Keep the ampoules or vials in the outer carton.

Once the Venofer ampoules or Venofer vials have been opened, they should be used immediately. After dilution with sodium chloride solution, the diluted solution should be used immediately.
Venofer will normally be stored for you by your doctor or the hospital.

6. Contents of the pack and other information

What Venofer contains

- The active substance is iron (as iron sucrose). Each millilitre contains 20 mg iron.
- The other ingredients are water for injections and sodium hydroxide.

What Venofer looks like and contents of the pack

Venofer is a dark brown, non transparent, aqueous solution.
Venofer comes in following pack-sizes:

- 5 Glass ampoules of 5 mL. Each ampoule of 5 mL corresponds to 100 mg of iron.
- 5 Glass vials of 5 mL. Each vial of 5 mL corresponds to 100 mg of iron.

Not all pack-sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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The following information is intended for healthcare professionals only:

Administration
Monitor carefully patients for signs and symptoms of hypersensitivity reactions during and following each administration of Venofer.

Venofer should only be administered when staff trained to evaluate and manage anaphylactic reactions is immediately available, in an environment where full resuscitation facilities can be assured. The patient should be observed for adverse effects for at least 30 minutes following each Venofer administration.

Mode of Administration:
Venofer must only be administered by the intravenous route. This may be by drip infusion, slow injection or directly into the venous line of the dialysis machine.

Paravenous leakage must be avoided because leakage of Venofer at the injection site may lead to pain, inflammation and brown discoloration of the skin.

Intravenous drip infusion:
Venofer must only be diluted in sterile 0.9% m/V sodium chloride (NaCl) solution. Dilution must take place immediately prior to infusion and the solution should be administered as follows:

Venofer dose (mg of iron)	Venofer dose (mL of Venofer)	Maximum dilution volume of sterile 0.9% m/V NaCl solution	Minimum Infusion Time
50 mg	2.5 mL	50 mL	8 minutes
100 mg	5 mL	100 mL	15 minutes
200 mg	10 mL	200 mL	30 minutes

For stability reasons, dilutions to lower Venofer concentrations are not permissible.

Intravenous injection:
Venofer may be administered by slow intravenous injection at a rate of 1 mL undiluted solution per minute and not exceeding 10 mL Venofer (200 mg iron) per injection.

Injection into venous line of dialysis machine:
Venofer may be administered during a haemodialysis session directly into the venous line of the dialysis machine under the same conditions as for intravenous injection.

Incompatibilities

Venofer must not be mixed with other medicinal products except sterile 0.9% m/V sodium chloride solution. There is the potential for precipitation and/or interaction if mixed with other solutions or medicinal products. The compatibility with containers other than glass, polyethylene and PVC is not known.

Shelf life and storage

Do not use this medicine after the expiry date which is stated on the carton after EXP. Do not store above 25°C. Do not freeze. Store in the original package.

Shelf life after first opening of the container
From a microbiological point of view, the product should be used immediately.

Shelf life after dilution with the sterile 0.9% m/V sodium chloride (NaCl) solution
From a microbiological point of view, the product should be used immediately after dilution.

Instruction for use and handling

Ampoules or vials should be visually inspected for sediment and damage before use. Use only those containing a sediment free and homogenous solution. The diluted solution must appear as brown and clear.
Any unused product or waste material should be disposed of in accordance with local requirements.