1.3.2 PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you are given Venofer®.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- **Venofer®** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

S3

Venofer® 5 ml ampoules

Each 5 ml of **Venofer®** contains 100 mg iron in the form of iron(III)-hydroxide sucrose complex.

WHAT VENOFER® CONTAINS

The active substance is iron (as iron sucrose).

Each 5 millilitre ampoule contains 100 mg iron.

Each 5 millilitre ampoule contains 1,45 g sugar.

The other ingredients are water for injections and sodium hydroxide.

Contains no preservatives.

WHAT VENOFER® IS USED FOR

Venofer® is used for the treatment of patients with iron deficiency, when oral iron preparations are ineffective or cannot be used.

Before administration, your doctor will perform a blood test to calculate the dose of **Venofer®** you require.

BEFORE YOU RECEIVE VENOFER®

You must not be given Venofer®:

- if you are allergic (hypersensitive) to iron sucrose or any of the other ingredients of **Venofer®**.
- if you have anaemia which is not caused by a shortage of iron.
- if you have too much iron in your body or a problem in the way your body uses iron.
- if you have ever had asthma, eczema or other allergies.
- if you have any infections.
- if you have liver problems.
- if you are a child. This is because it has not been shown that **Venofer®** is safe in children.
- if you are breast feeding your baby. This is because it has not been shown that **Venofer®** is safe for the breastfed child.
- if you are in the first three months of pregnancy.

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

Take special care with Venofer®:

Children:

The use of **Venofer®** has not been adequately studied in children and therefore **Venofer®** is not recommended for use in children.

Pregnancy and breastfeeding:

Venofer® must not be given during the first three months of pregnancy. Your doctor will decide if **Venofer®** can be used during the fourth to ninth months of pregnancy.

Venofer® is not recommended for use in breastfeeding women.

If you are pregnant or breastfeeding your baby while taking **Venofer®**, please consult your doctor, pharmacist or other health care professional for advice.

Driving and using machinery:

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.

Taking other medicines with Venofer®:

Venofer® should not be given together with oral iron preparations.

If you are taking other medicines on a regular basis including complementary or traditional medicines, the use of **Venofer®** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

HOW VENOFER® IS GIVEN®

Venofer® will be given to you by a doctor or other health care professional.

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.

If you have never had **Venofer®** before, you will have a small test dose. This is to check that you are not allergic to it.

How Venofer® is given:

Venofer® can be given in 3 different 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 limb of the dialyser.

You must not receive more than 2 ampoules of **Venofer®** (100 mg iron) per treatment. **Venofer®** is a brown liquid and so the injection or infusion will look brown.

Children:

Venofer® is not recommended for use in children.

If you are given more Venofer® than you should have:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison centre.

POSSIBLE SIDE EFFECTS

Venofer® can cause side effects.

Allergic reactions (affects less than 1 in 1000 people):

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.

Tell your doctor or nurse straight away if you think you are having an allergic reaction.

Other side effects include:

Frequent:

• Changes in your taste such as a metallic taste. This does not usually last very long.

Less frequent:

• Fast pulse rate

• Headache or feeling dizzy

• Low blood pressure and collapse

• Pounding heart beat (palpitations)

• Stomach pain or diarrhoea.

• Feeling sick (nausea) or being sick (vomiting).

• Wheezing, difficulty in breathing.

• Itching, hives, rash or skin redness.

• Muscle cramps or muscle pain.

• Flushing.

• Fever or shivering.

• Chest pain and chest tightness.

• Reactions around the site of injection such as inflammation, a feeling of burning and swelling.

• Fainting.

• Loss of consciousness.

• Tingling or “pins and needles”.

• A feeling of burning.

• Swelling (dropsy).

• Pain in your joints.

• Swelling of hands and feet.

• Tiredness, weakness or general feeling of illness.

Other side effects include feeling less alert, light-headed or confused; swelling of your joints, face and tongue; increased sweating; back pain.

If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

Not all side effects reported for **Venofer®** are included in this leaflet. Should your general health worsen while taking **Venofer®**, please consult your doctor, pharmacist or other health care professional for advice.

STORING AND DISPOSING OF VENOFER®

Store all medicines out of reach of children.

Store at or below 25 °C. Do not freeze. Store in the original container.

Do not use after the expiry date stated on the carton.

Once the **Venofer®** ampoules have been opened, they must be used immediately. After dilution with sterile sodium chloride solution, the diluted solution should be used immediately.

Venofer® will normally be stored for you by your doctor or the hospital.

PRESENTATION OF VENOFER®

Glass ampoules of 5 ml. Pack sizes of 5 ampoules.

IDENTIFICATION OF VENOFER®

Venofer® is a brown, aqueous solution

REGISTRATION NUMBER

32/8.3/0166

NAME AND ADDRESS OF REGISTRATION HOLDER

PHARMACARE LIMITED

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Woodmead 2191

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