**Patient information leaflet**

**AMIFER® IV**
**20 mg of iron/ml**

**Solution for injection or concentrate for solution for infusion**

Iron sucrose

**Read all of this leaflet carefully before you start taking 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 or pharmacist. This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

**1. What Amifer® IV is and what it is used for**

Amifer® IV contains iron in the form of iron sucrose. Amifer® IV is used when you do not have enough iron in your body. Amifer® IV is prescribed when you cannot ingest iron – for example, when iron tablets cause nausea, vomiting, or stomach discomfort, or if you have taken iron by mouth without getting the desired effect (ATC code: B03AC).

**2. What you need to know before you take Amifer® IV**

**Do not take Amifer® IV:** if you are allergic (hypersensitive) to the product or any of its excipients (listed in section 6); or if you have a history of severe allergy (hypersensitivity) to other injectable irons; or if your anaemia is not due to iron deficiency; or if you have too much iron in your body or a problem in the way your body uses iron. **Warnings and precautions:** Before administering Amifer® IV, you should be careful: if you have a history of drug allergy; if you have systemic lupus erythematosus; or if you have rheumatoid arthritis; or if you have asthma, eczema, or other severe allergies; if you have an infection; if you have liver disease. If you are not sure if any of above apply to you, talk to your doctor or pharmacist. **Other medicines and Amifer® IV:** 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. Amifer® IV may affect the way other medicines work. Similarly, certain other medications may affect the way Amifer® IV works. In particular, tell your doctor or pharmacist if you are taking: oral medicines that contain iron. These may not work if taken at the same time as Amifer® IV. **Pregnancy, breast-feeding and fertility:** Amifer® IV 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. Talk to your doctor if you become pregnant during the treatment. Your doctor will decide whether or not the treatment should be continued. Talk to your doctor before using Amifer® IV if you are breast-feeding. If you are pregnant or breast-feeding, ask your doctor or pharmacist for advice before taking any medicine. **Driving vehicles and using machines:** Dizziness, feelings of confusion or intoxication may occur after administration of Amifer® IV. If this happens, do not drive a vehicle or operate tools or machinery. Ask your doctor if your are not sure.

**3. How Amifer® IV is given**

The doctor will decide how much Amifer® IV to administer, how often you will receive the injections and for how long the treatment will last. The doctor will perform a blood test to determine the dose. Your doctor or nurse will administer Amifer® IV in one of the three following ways: by slow intravenous injection, one to three times per week; or by intravenous infusion (drip), one to three times per week; or during a haemodialysis session: directly in the venous line of the dialysis machine. Amifer® IV will be administered in a structure where immunoallergic side effects can receive appropriate and prompt treatment. You will be observed by your doctor or nurse for at least 30 minutes after each administration. Amifer® IV is a brown liquid and so the injection or infusion will look brown in colour. **Use in children:** Amifer® IV is not recommended for use in children. If you are given more Amifer® IV than should, then contact your doctor as soon as possible.

**4. Possible side effects**

Like all medicines, this medicine may cause side effects, although not everybody gets them. **Allergic reactions** (may affect up to 1 in 100 people): If you have an allergic reaction, tell your doctor or nurse straight away. Symptoms include: low blood pressure (dizziness, feeling light-headed or faint), or swelling of the face, difficulty breathing. Tell your doctor or nurse straight away if you think you are having an allergic reaction. **Other side effects:** Common (may affect up to 1 in 10 people): changes in your taste, specifically a metallic taste, which usually does not last very long, low or high blood pressure, feeling sick (nausea), reactions around the injection/infusion site such as pain, irritation, itching, haematoma or discolouration following the leakage of the injected product into the skin. Uncommon (may affect up to 1 in 100 people): headache or dizziness, stomach ache or diarrhoea, vomiting, wheezing, difficulty 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 the 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, excessive 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 the 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. If you get any side effects, talk to your doctor or nurse. This also includes any side effects not listed in this leaflet.

**5. How to store Amifer® IV**

Store below 30°C. Do not freeze. Keep out of reach and sight of children. Do not use after the expiry date, stated on the packaging (Exp.). The expiry date refers to the last day of that month. Any unused product or waste material should be disposed of in accordance with the regulations in force. After opening, Amifer® IV ampoules should be used immediately. After dilution in sodium chloride solution, the diluted solution should be used immediately. Normally, your doctor or the hospital will store Amifer® IV for you.

**6. Contents of the pack and other information**

**What Amifer® IV contains:** The active substance is iron (in the form of an iron sucrose complex). Each millilitre contains 20 mg of iron. The other ingredients are sodium hydroxide and water for injection. **What Amifer® IV looks like and contents of the pack:** Aqueous, non-transparent, dark brown solution; presented in a 5 ml clear glass ampoule, packaged in a pack-size of 5 ampoules. Each 5 ml ampoule corresponds to 100 mg of iron.

Amifer® IV is available by prescription only.

**7. Manufacturer:** Mefar Ilaç Sanayii A.Ş. Ramazanoğlu Mah. Ensar Cad. No. 20; Kurtköy-Pendik, Istanbul, Turkey

**8. Released by:** Santa Farma İlaç Sanayi A.Ş., GEBKİM 41455 Dilovası-KOCAELİ, Turkey

**9. Marketing Authorisation Holder:** Dafra Pharma GmbH, Mühlenberg 7, 4052 Basel, Switzerland**.**

**10. This leaflet was last revised:** December 2017.

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