AMIFER® IV

QUALITY INJECTABLE IRON

WITH CLEAR BENEFITS FOR PATIENTS:

Who do not tolerate oral iron

Who have difficulties taking oral iron

Who have gastrointestinal absorption problems

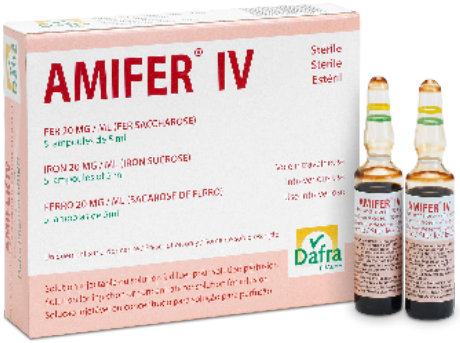
In those for whom oral preparations are less effective

In patients with heart failure

In patients with severe postoperative bleeding

When losses are greater than the oral absorption capacity

When the patient's clinical situation necessitates rapid iron administration



For the complete SMPC, consult www.dafrapharma.com

3FIAMIVE 2022

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www.dafrapharma.com

AMIFER® IV

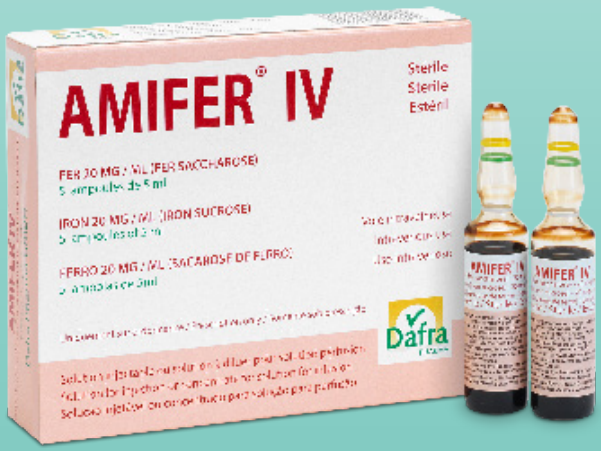
200 mg of iron / ml

EUROPEAN GMP

Injectable solution
or concentrate for solution for infusion

Each 5 ml ampoule of AMIFER® IV contains 100 mg of iron in the form of iron sucrose

QUALITY INJECTABLE IRON



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AMIFER® IV – POSOLOGY and METHOD OF ADMINISTRATION

The cumulative dose of AMIFER® IV should be calculated for each patient individually and should not be exceeded. This dose corresponds to the total iron deficit (mg) and is determined by the patient's haemoglobin level and bodyweight. (Ganzoni formula)

Ganzoni formula

Total iron deficit (mg) = bodyweight (kg) x (target Hb - actual Hb)(g/dl) x 2.4 + iron reserves (mg)

- For a bodyweight < 35 kg: target Hb = 13 g/dl and iron reserves = 15 mg/kg bodyweight
- For a bodyweight> 35 kg: target Hb = 15 g/dl and iron reserves = 500 mg

ADMINISTRATION POSSIBILITIES				
INTRAVENOUS BOLUS	**INTRAVENOUS INFUSION**			
AMIFER® IV by slow intravenous injection at a rate of 1 ml of undiluted solution per minute. Never exceed 10 ml of AMIFER® IV (200 mg of iron) per injection.	DILUTE ONLY in physiological saline (0.9 NaCl m/V). Dilution should be done immediately before infusion and the solution should be administered as follows:			
HAEMODIALYSIS DIRECTLY INTO THE VENOUS LINE	**Dose (mg of iron)**	**Dose (ml)**	**Maximum dilution volume**	**Minimum infusion volume**
AMIFER® IV by slow intravenous injection at a rate of 1 ml of undiluted solution per minute. Never exceed 10 ml AMIFER® IV (200 mg of iron) per injection.	50 mg	2,5 ml	50 ml	8 min
	100 mg	5 ml	100 ml	15 min
	200 mg	10 ml	200 ml	30 min

For stability reasons, never proceed with dilutions of weaker concentrations.

AMIFER® IV

Parenteral iron appropriate to correct iron deficiencies with or without anemia.

AMIFER® IV is used when oral treatment of iron deficiency is not sufficient or not possible, such as :

- **When the patient's clinical situation necessitates rapid iron administration**
- **In patents who cannot tolerate oral iron treatment or who do not follow the prescription**
- **In inflammatory bowel disease, when oral iron preparations are ineffective**
- **In chronic nephropathy or where oral iron preparations are less effective**

NUMBER of AMIFER® IV AMPOULES to be administered based on weight and baseline hemoglobin											
body weight (kg)	baseline hemoglobin level (g/dl)										
	5	5,5	6	6,5	7	7,5	8	8,5	9	9,5	10
20	7	7	6	6	6	6	5	5	5	5	4
25	9	8	8	8	7	7	7	6	7	6	6
30	10	10	10	9	9	8	8	8	8	7	7
35	13	13	13	12	12	11	11	10	11	10	9
40	15	14	14	13	13	12	12	11	12	10	10
45	16	15	15	14	14	13	13	12	13	11	10
50	17	16	16	15	15	14	13	13	13	12	11
55	18	18	17	16	16	15	14	14	14	12	12
60	19	19	18	17	17	16	15	14	15	13	12
65	21	20	19	18	17	17	16	15	16	14	13
70	22	21	20	19	18	18	17	16	17	14	13
75	23	22	21	20	19	19	18	17	18	15	14
80	24	23	22	21	20	19	18	17	18	16	15
85	25	24	23	22	21	20	19	18	19	16	15
90	27	26	24	23	22	21	20	19	18	17	16
	maximum 2 ampoules per day - maximum 1 day out of 2										

PREGNANCY, LACTATION AND FERTILITY

AMIFER® IV has not been tested in women during the first three months of pregnancy. It is important to inform the physician if the women is pregnant, thinks she may be or plans to be. In the event of pregnancy during treatment, the physician will decide if the treatment can be continued or discontinued. When the woman is breastfeeding, this should be discussed before any administration of **AMIFER® IV**.

DRIVING AND USING MACHINES

Dizziness or a feeling of confusion or intoxication can occur after the administration of **AMIFER® IV**. If this is the case, the patient should not drive or use tools or machines.

POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. **Allergic reactions** (Symptoms include: low blood pressure (dizziness, feeling of inebriation or fainting), or swelling of the face, difficulty breathing) **Other side effects**: taste changes, especially a metallic taste, not usually lasting a very long time, reduction or increase in blood pressure, need to vomit (nausea), reactions around the injection/infusion site such as pain, irritation, itching, bruising or discoloration following leaking of the injected product into the skin. Uncommon: headache or dizziness, stomach ache or diarrhea, vomiting, wheezing, difficulty breathing, itching, rash, muscle spasms, cramps or pain, prickling or tingling, reduced sense of touch, inflammation of a vein, feeling hot, burning, constipation, joint pain, limb pain, back pain, chills, weakness, fatigue, swelling of hands and feet, pain, increased level of liver enzymes (ALT, AST, GGT) in the blood, increased serum ferritin levels. Rare: fainting, feeling sleepy or falling asleep, pounding heart (palpitations), urine discolouration, chest pain, excessive sweating, fever, increased lactic dehydrogenase in the blood. Other side effects of unknown frequency include: decreased alertness, feeling confused, loss of consciousness, anxiety, tremor, swelling of the face, mouth, tongue or throat which may cause difficulty in breathing, decreased pulse, rapid pulse, circulatory collapse, inflammation of a vein causing a blood clot, acute narrowing of the airways, itching, hives, rash or redness of the skin, cold sweat, general feeling of being unwell, pale skin, sudden onset, life-threatening allergic reactions. If a patient feels any side effects, the should talk to the physician or nurse. This also applies to any side effects not mentioned in the leaflet.