

## Patient Information Leaflet

### AMIFER® Iron Syrup 200 ml

**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. If you get any side effects, talk to your doctor or pharmacist. This medicine has been prescribed just for you. Never offer your medicine to other people. It may not be suitable for them even if their symptoms seem the same as yours.

**Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.**

#### 1. What AMIFER® Iron Syrup is and what it is used for

AMIFER® syrup is used to treat and prevent iron and folic acid deficiency. This syrup can be used by people with an iron deficiency or low dietary iron, during pregnancy, after delivery for prevention of anemia, of iron and folic acid deficiency (ATC code: B03AE1).

#### 2. What you need to know before you take AMIFER® Iron Syrup

**You should check with your doctor before taking this medication:**

- If you are frequently receiving blood transfusions.
- If you have a blood disorder, if you suffer from epilepsy, if you suffer from digestive system or stomach problems.

**Do not take it:**

- If you are allergic to any of the ingredients.
- In cases of iron overload problems (haemochromatosis, hemosiderosis, chronic hemolysis) and disturbances to iron utilisation (sideroachrestic anemias, lead poisoning anemias, thalassemias).
- In cases of megaloblastic anemia resulting from isolated vitamin B12 deficiency or isolated folic acid deficiency.

**Interactions with other medicinal products:**

- Some other medicines may not be combined with ferric ammonium citrate/folic acid syrup. Your doctor is aware of this and will alter your treatment as needed. However, it is very important that you tell your doctor about all the medicines you are taking, including those obtained without a doctor's prescription.
- Simultaneous administration of antacids, phosphates, carbonates, oxalates, calcium and some other antibiotic drugs (tetracyclines) may decrease the effect of iron.
- The effect of penicillamine, fluoroquinolones, sodium etidronate, sodium clodronate, some antibiotic drugs (tetracyclines), methotrexate, trimethoprim, and pyrimethamine may be decreased.

**Pregnancy and breast-feeding:** AMIFER® Iron Syrup can be used safely during pregnancy and breastfeeding.

**Driving or using machinery:** Adverse effects on the ability to drive or operate machinery have not been observed.

**Overdose:** In case of overdose, contact your doctor or pharmacist immediately.

#### 3. How to take AMIFER® Iron Syrup

Dosage: Please follow your doctor's instructions on how and when to take this medicine. In doubt, contact your pharmacist or doctor.

**Guidelines for iron supplementation:**

- |                                         |                   |                               |
|-----------------------------------------|-------------------|-------------------------------|
| • Infants and children (0-13 years):    | 30 mg/day of iron | = 5 ml of AMIFER® Iron Syrup  |
| • Adolescents (14-18 years) and adults: | 60 mg/day of iron | = 10 ml of AMIFER® Iron Syrup |
| • Pregnancy and lactation:              | 60 mg/day of iron | = 10 ml of AMIFER® Iron Syrup |

**Guidelines to treat severe anemia**

- |                                         |                    |                                                 |
|-----------------------------------------|--------------------|-------------------------------------------------|
| • Adolescents (14-18 years) and adults: | 120 mg/day of iron | = 20 ml of AMIFER® Iron Syrup (during 3 months) |
| • Pregnancy and lactation:              | 120 mg/day of iron | = 20 ml of AMIFER® Iron Syrup (during 3 months) |

• **Shake well before use!**

- Do not drink milk, dairy products or tea at the same time, but wait at least two hours before you use these drinks.
- Always take the medicine immediately after a meal, as this may prevent gastric discomfort.
- Try to take your medication at the same time each day. This makes it easier to remember.
- **Duration of use:** Keep taking this syrup until your doctor tells you to stop.

**What to do if you missed a dose?** Don't worry if you missed a dose. Take your next dose at the usual time. If you keep forgetting your syrup, speak to your doctor.

#### 4. Possible side effects

AMIFER® Iron Syrup may occasionally cause side effects in some patients:

- These may include nausea, vomiting, constipation, diarrhoea. Dark coloration of the stool is common and harmless.
- Allergic reactions rarely occur.

Tell your doctor if you suffer badly or develop any other unusual problems, while taking this medication.

#### 5. How to store AMIFER® Iron Syrup: Shelf life: 2 years. Store the syrup in the original packaging at a temperature below 30°C. Protect from light. Keep out of reach and sight of children. Do not use this medicine if the expiry date printed on the pack or bottle (Exp.) has passed.

#### 6. Further information

**What AMIFER® Iron Syrup contains:** 5 ml contains: Ammonium ferric citrate 172.41 mg (equivalent to 30 mg elemental iron), Folic acid 2.5 mg, Vitamin B12 (cyanocobalamin) 0.02 mg. Other ingredients: potassium sorbate, sodium chloride, citric acid anhydrous, orange flavour, vanilla flavour, mint flavour, sucralose, ethanol, glycerol, Eurocert ponceau 4R E124, sorbitol syrup.

**AMIFER® Iron Syrup** is available without prescription.

**NAME OF MANUFACTURER:** Sofarimex, Indústria Química e Farmacêutica S.A. Av das Indústrias, Alto de Colaride, 2735-213 Cacém, Portugal.

**REGISTRATION/LICENCE HOLDER:** Dafra Pharma GmbH, Mühlenberg 7, 4052 Basel, Switzerland.

**DATE OF REVISION OF THE TEXT:** February 2016.