

Patient Information Leaflet

AMIFER® Junior Iron Syrup 150 ml

Read all of this leaflet carefully before you start taking this medicine because it contains important information for your child or for you. Keep this leaflet. You may need to read it again. If you have any further questions, ask your Health Care Professional. If you or your child get any side effects, talk to your Health Care Professional. This medicine is available without prescription. Never offer your medicine to other people. It may not be suitable for them even if their symptoms seem the same.

Always take this medicine exactly as described in this leaflet or as your Health Care Professional has told you.

1. What is AMIFER® Junior, and what it is used for? 5 ml (1 spoon) of AMIFER® Junior contains iron III hydroxide polymaltose complex, equivalent to 50 mg of elementary iron. It is used to treat and prevent all iron deficiencies from various origins and iron deficiency anemia, and in iron deficiency treatment in childhood, but also during pregnancy and lactation. **AMIFER® Junior** is a medication intended to treat infants and children; it can however be taken also by adults (ATC Code: B03AB05).

2. What you need to know before you take AMIFER® Junior.

Do not take it if your child or you:

- are allergic to iron or to any of the ingredients,
- have iron overloading (hemochromatosis, chronic hemolysis),
- have anemia, which is not accompanied by iron deficiency (such as hemolytic anemia),
- have iron use disorder (lead anemia, sideroachrestic anemia),
- have thalassemia,
- have progressive and chronic arthritis,
- have conditions, requiring regular and continuous blood transfusions,
- have a HIV infection without clinically proven iron deficiency anemia,
- have severe liver and kidney diseases.

Use AMIFER® Junior with caution:

- if you have gastric ulcer (your Health Care Professional will decide whether to use AMIFER® Junior or not),
- caution must be exercised in case of alcoholism and conditions which disturb iron absorption from intestines,
- caution must be exercised in case of alcoholism and conditions which disturb iron absorption from intestines,
- AMIFER® Junior contains sugar and sorbitol (E420): if you have been told by your Health Care Professional that your child or you have intolerance to certain sugars, you should contact your Health Care Professional before taking this product,
- AMIFER® Junior contains methyl paraben (E216) and propyl paraben (E218), AMIFER® Junior may yield (possibly delayed) allergic reactions.

In case these warnings apply to you or your child, even if for any period in the past, please consult your Health Care Professional. During administration of oral iron formulations, the color of stool may darken; this is normal and does not require any measures, it does not cause false positive results during tests for occult blood in stool, therefore, there is no need to discontinue treatment during this test,

In various diseases and in cancer-related anemia, the taken iron is stored in liver, yet following the treatment of these diseases and cancer, it departs from liver and becomes useable.

Interactions with other medicinal products: if your child or you are using or have recently used any prescription or nonprescription pharmaceuticals please report these to your Health Care Professional.

Pregnancy and breast-feeding: AMIFER® Junior can be used safely during pregnancy and breastfeeding if your Health Care Professional recommends it. Consult your Health Care Professional immediately in case you realize that you are pregnant during treatment. Consult your Health Care Professional before using AMIFER® Junior during lactation: iron is excreted into breast milk

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

3. How to take AMIFER® Junior?

Dosage: Please follow the instructions of your Health Care Professional on how and when to take this medicine. Recommended dosage in children is 2 mg iron/kg/day.

- | | | |
|--|--|--------------------------|
| • Infants and children (6 months - 2 years): | 1/4 spoon (= 1.25 ml) once a day | (= 12.5 mg of iron). |
| • Children (2 - 5 years): | 1/2 spoon (= 2.5 ml) 1 - 2 times a day | (= 25 - 50 mg of iron). |
| • Children (6 -12 years): | 1 spoon (= 5 ml) 1 - 2 times a day | (= 50 - 100 mg of iron). |
| • Adolescents, adults and elderly: | 1 spoon (= 5 ml) 2 times a day | (= 100 mg of iron). |

It must be used for the term, recommended by the Health Care Professional. Following the elimination of the symptoms of iron deficiency, it must be used for at least an additional month for replenishment of stores.

Administration route and method: AMIFER® Junior is only for oral administration. It must be taken with or after meals, it may be taken by mixing with fruit or vegetable juices; not with milk (iron formulations must be taken at least 2 hours after milk or calcium products). **What to do if you did not take or give a dose?** Don't worry, take or give the next dose at the usual time. Do not take or give double doses to compensate for forgotten doses. **If you have taken or given more AMIFER® Junior than you should have:** diarrhea, stomach ache and vomiting may be seen with overdose and in more severe cases metabolic acidosis, severe muscle spasms and coma may be seen. Accidental administration of iron-containing products causes fatal (deadly) toxicity in children below 6 years of age. In case of overdose promptly consult your Health Care Professional or poison control center.

4. Possible side effects: AMIFER® Junior may occasionally cause side effects in some patients.

- If any of the following occurs, stop taking AMIFER® Junior and inform your Health Care Professional IMMEDIATELY and refer to the emergency service of the nearest hospital: difficulty in breathing, swelling in face, lips, tongue or throat, sudden decrease in blood pressure, widespread and severe flushing, itching (urticaria), asthma; it means that you have a serious allergy to AMIFER® Junior (these serious side effects are seen very rarely).
 - If you experience any of the following side effects, inform your Health Care Professional: indigestion; abdominal discomfort; nausea, vomiting; burning sensation in stomach; bitter fluid in mouth; mild abdominal pain; itching blisters on skin, rashes, redness; headache; change in urine and stool color (these are mild side effects of AMIFER® Junior).
 - In case you observe any side effects, which are not mentioned in these usage instructions, please inform your Health Care Professional.
5. **How to store AMIFER® Junior:** Store in the original packaging at a temperature below 25°C. 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. In case you notice irregularities on the product and/or package, do not use it.
6. **Further information**
What does AMIFER® Junior contains? 5 ml (1 spoon) contains iron III hydroxide polymaltose complex, equivalent to 50 mg elementary iron. Other ingredients: sugar, sorbitol 70 % (E420), methyl paraben (E218), propyl paraben (E216), cream flavor and deionized water. It is presented in honey-colored glass bottles, containing 150 ml syrup, together with a plastic spoon. It has a characteristic smell, and appears as dark red-brown syrup.
AMIFER® Junior is available without prescription.
7. **NAME OF MANUFACTURER:** Santa Farma İlaç Sanayi A.Ş. GEBKİM 41445 Dilovası-KOCAELİ-TURKEY
8. **REGISTRATION/LICENCE HOLDER:** Dafra Pharma GmbH, Mühlenberg 7, 4052 Basel, Switzerland.
9. **DATE OF REVISION OF THE TEXT:** August 2017.