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**Package leaflet: Information for the user****Ferro AIWA 100 mg  
Film-coated tablet**

dried iron(II)-sulphate

**For use in adults**

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told 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 includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

1. What Ferro AIWA 100 mg is and what it is used for
2. What you need to know before you take Ferro AIWA 100 mg
3. How to take Ferro AIWA 100 mg
4. Possible side effects
5. How to store Ferro AIWA 100 mg
6. Contents of the pack and other information

**1. What Ferro AIWA 100 mg is and what it is used for**

Ferro AIWA 100 mg is used to treat iron deficiency.

**2. What you need to know before you take Ferro AIWA 100 mg****Do not take Ferro AIWA 100 mg**

- if you are allergic to iron sulphate or any of the other ingredients of this medicine (listed in section 6).
- if you suffer from anaemia caused by infections or cancer, unless you also have iron deficiency.
- if you have too much iron in your blood (raised iron levels) and iron utilisation disorders.

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Ferro AIWA 100 mg.

Due to the risk of mouth ulcers and tooth discoloration, the tablets must not be sucked, chewed or left in the mouth for too long. They should be swallowed whole with some water. If you are not able to follow these directions or have difficulty swallowing, talk to your doctor.

**Take special care with Ferro AIWA 100 mg:**

- if you suffer from inflammation or ulcers of the gastrointestinal (stomach/gut) lining. Talk to your doctor before taking Ferro AIWA 100 mg. He/she will carefully weigh up the benefit of treatment against the risk of worsening your gastrointestinal disease.
- if you are also using dietary or other iron salt supplements. To avoid the risk of possible iron overdose, talk to your doctor before taking Ferro AIWA 100 mg.

**Other medicines and Ferro AIWA 100 mg**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Iron salts such as Ferro AIWA 100 mg

- reduce the uptake of
  - certain antibiotics (tetracyclines),
  - penicillamine (used to treat rheumatic disease),
  - levodopa (used in Parkinson's disease),
  - methyldopa (used to treat high blood pressure),
  - thyroxine (thyroid hormone) in patients treated with thyroxine.
- affect the uptake of quinolone antibiotics (e.g. ciprofloxacin, levofloxacin, norfloxacin, ofloxacin).
- may increase the irritant effect on the gastrointestinal lining when taken together with non-steroidal anti-inflammatory drugs (including, for example, a number of medicines commonly used for pain, fever and inflammation).

Iron uptake is reduced by the following medicines, if taken at the same time:

- cholestyramine (used to lower high blood fat levels),
- antacids (calcium, magnesium and aluminium salts used to bind stomach acid),
- or calcium and magnesium supplements.

You should not take Ferro AIWA 100 mg within 2-3 hours after taking any of the above substances.

**Ferro AIWA 100 mg with food and drink**

You should take Ferro AIWA 100 mg 1 hour before or possibly between meals, as food may affect iron uptake.

Iron-binding substances such as phytates (e.g. from cereals), phosphoric acid salts (e.g. from milk), oxalic acid salts (e.g. from spinach or rhubarb), tannic acids (tea) or coffee inhibit the uptake of iron by the body.

**Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Treatment with Ferro AIWA 100 mg should be administered only after a careful benefit/risk assessment and consultation with your doctor. The high dosage of two Ferro AIWA 100 mg film-coated tablets per day should not be prescribed over prolonged periods of time.

**Breast-feeding**

Similarly during breast-feeding, Ferro AIWA 100 mg should be prescribed only after a careful benefit/risk assessment and after consultation with your doctor.

**Driving and using machines**

There are no known effects.

**Ferro AIWA 100 mg contains lactose and sucrose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

**3. How to take Ferro AIWA 100 mg**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults take 1 Ferro AIWA 100 mg film-coated tablet twice daily.

This medicine is not intended for use in children and adolescents under 18 years of age.

The film-coated tablets should be taken in the morning on an empty stomach or 1 hour before meals. They should be swallowed whole with plenty of liquid to prevent possible damage to the mucous membranes caused by the tablets getting stuck.

Swallow the tablet whole with water. Do not suck or chew the tablet and do not leave the tablet too long in your mouth.

The amount of iron to be supplied to the body depends on the stage of your iron deficiency. Please ask your doctor.

The duration of treatment depends on the nature and severity of your condition. In general, iron therapy over a period of at least 8 weeks is required to achieve successful treatment. After blood levels (haemoglobin) have returned to normal, treatment should be continued for a further 6-8 weeks to replenish (top up) your iron reserves.

If you have the impression that the effect of Ferro AIWA 100 mg is too strong or too weak, please talk to your doctor or pharmacist.

For people with kidney or liver disease

There are no adequate data to make any definite dosage recommendations for people with impaired kidney/liver function.

**If you take more Ferro AIWA 100 mg than you should**

Tell your doctor.

**If you forget to take Ferro AIWA 100 mg**

In general, medicines should always be taken as prescribed by the doctor. Please do not make up for forgotten doses by doubling the number of film-coated tablets. In this case, just continue to take your tablets as originally intended.

**If you stop taking Ferro AIWA 100 mg**

Please contact your doctor or pharmacist in advance, as he/she can best assess any possible effects on your state of health.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common: may affect up to 1 in 10 patients treated

Dark discoloration of the stools is often observed after taking oral iron supplements, but is completely harmless.

Uncommon: may affect up to 1 in 100 patients treated

Gastrointestinal upset occasionally occurs, e.g. loss of appetite, gastric pressure, bloating and constipation.

Note:

Constipation can be corrected with a balanced diet.

Rare: may affect up to 1 in 1,000 patients treated

In rare cases, hypersensitivity reactions (e.g. skin changes) may occur.

Not known: (frequency cannot be estimated from the available data)

Mouth ulcers (due to incorrect use, if the tablets are chewed, sucked or left in the mouth for too long). Older patients or patients with swallowing difficulties are also at risk of ulcers in the throat, oesophagus (the tube connecting the mouth and stomach) or bronchi (the main airway branches of the lungs), if the tablets get into the respiratory tract.

If affected, you should stop taking this medicine and consult your doctor.

### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via *Bundesinstitut für Arzneimittel und Medizinprodukte* (Federal Institute for Drugs and Medical Devices), *Abt. Pharmakovigilanz* (Department of Pharmacovigilance), Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, website: [www.bfarm.de](http://www.bfarm.de). By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Ferro AIWA 100 mg

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

Do not store above 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

### What Ferro AIWA 100 mg contains

- The active substance is: dried iron(II) sulphate
- One film-coated tablet contains: 302.237 - 309.106 mg dried iron(II) sulphate (equivalent to 100 mg iron(II) ions)
- The other ingredients are:  
Maltodextrin, calcium stearate, lactose monohydrate, copovidone, macrogol 4000, talc, calcium carbonate E170, cocoa butter, magnesium stearate [vegetable], shellac, titanium dioxide E171, cellulose powder, maize starch, carboxymethyl starch sodium (type A), sodium dodecyl sulphate, sucrose, povidone K25, iron oxides and hydroxides (E172)

### What Ferro AIWA 100 mg looks like and contents of the pack

The film-coated tablets are round, convex and brown in colour.

Original pack with 20 film-coated tablets.  
Original pack with 50 film-coated tablets.  
Original pack with 100 film-coated tablets.  
Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

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Made in Germany

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Special packs:  
Pack of 20 film-coated tablets and the imprint "Sample: not for resale" on the carton.