



# IronFol

100 mg / 0,35 mg chewable tablets

Iron as Iron (III) hydroxide polymaltose complex / Folic acid

**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.
- 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 **IronFol** is and what it is used for
2. What you need to know before you take **IronFol**
3. How to take **IronFol**
4. Possible side effects
5. How to store **IronFol**
6. Contents of the pack and other information

### 1. What **IronFol** is and what it is used for

It is used in women before and during pregnancy, and during breast-feeding to:

- Treat iron deficiency;
- Prevent iron and folic acid deficiency

You must talk to a doctor if you do not feel better or if you feel worse.

### 2. What you need to know before you take **IronFol**

#### Do not take **IronFol**:

- If you are allergic (hypersensitive) to Iron (III) hydroxide polymaltose complex, folic acid or any of the other ingredients of this medicine (listed in section 6);
- If you suffer from excessive amount of iron in the body;
- If you have disturbed use of iron by the body;
- If you have a reduced number of red blood cells (anemia), not caused by iron deficiency, such as due to increased red blood cells breakdown; vitamin B12 deficiency.

### Warnings and Precautions

Talk to your doctor or pharmacist before taking **IronFol** if you have:

- an infection or tumor
- a vitamin B12 deficiency

Folic acid contained in **IronFol** chewable tablets may mask a deficiency of vitamin B12.

Dark discolouration of the faeces may occur during

treatment with **IronFol chewable tablets**, however, this is harmless.

### Other medicines and **IronFol**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The following medicines can affect or be affected by **IronFol chewable tablets**:

- Injectable **iron** medicines;  
Additional injectable, iron medicines are not recommended.
- **Medicines to treat epilepsy**, particularly phenytoin;  
Inform your doctor before taking **IronFol chewable tablets**.
- **Chloramphenicol**: a medicine to treat bacterial infections.  
Your doctor will carefully monitor you if you take both medicines, because chloramphenicol can delay the response to treatment **IronFol**.

### Pregnancy, breast-feeding and fertility

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. Negative influence on the fetus or the woman during pregnancy or breast-feeding is unlikely according to the available data.

### Driving and using machines

**IronFol chewable tablets** has no or negligible influence on the ability to drive and use machines.

### Information for diabetics

Treatment with **IronFol chewable tablets** not expect to affect the daily dosage insulin in diabetic patients.

### 3. How to take **IronFol**

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

The recommended dose is:

- **Treatment of iron deficiency with reduced number of red blood cells**  
2 to 3 tablets once daily or divided into separate doses.

After normalisation of the red blood pigment (hemoglobin) value, continue with 1 tablet once daily at least the end of pregnancy. This will replenish the iron stores and provide the increased amount of iron required during pregnancy.

- **Treatment of iron deficiency with normal number of red**

**blood cells, and prevention of iron and folic acid deficiency**  
1 tablet once daily

#### **Method of administration**

Take **IronFol chewable tablets** during or immediately after a meal.

The tablets may be chewed or swallowed whole.

#### **Duration of use**

This is decided by the doctor and depends upon the degree of iron deficiency.

#### **If you take more IronFol chewable tablets than you should**

Contact your doctor or pharmacist if this occurs.

#### **If you forget to take IronFol chewable tablets**

Just take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

#### **If you stop taking IronFol chewable tablets**

Do not stop using the product sooner than recommended, as this may reduce the efficacy of treatment.

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.

Side effects can occur with the following frequency:

##### *Frequency of side effects:*

- Very common: more than 1 in 10 people are affected
- Common: between 1 in 10 and 1 in 100 people are affected
- Uncommon: between 1 in 100 and 1 in 1,000 people are affected
- Rare: between 1 in 1,000 and 1 in 10,000 people are affected
- Very rare: fewer than 1 in 10,000 people are affected
- Unknown frequency (can not be estimated from the data available).

##### **Very common**

- dark stool

##### **Common**

- diarrhea
- nausea
- indigestion

##### **Uncommon**

- vomiting
- constipation
- abdominal pain
- darkening teeth
- skin rash
- itch
- headache

#### **Reporting of side effects**

If you get any side effects talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store IronFol**

Keep this medicine out of the sight and reach of children. Store below 30 °C.

Store in the original package in order to protect from light and moisture.

Do not use this medicine after the expiry date which is stated on the carton after the abbreviation used for expiry date. The expiry date refers to the last day of that month. 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 IronFol chewable tablets contain**

The active substances are:

- Iron as Iron (III) hydroxide polymaltose complex
- Folic acid

##### **Each chewable tablet contains:**

- 100 mg Iron as Iron (III) hydroxide polymaltose complex;
- 350 micrograms folic acid.

The other ingredients are: Dextrates, Microcrystalline cellulose, Sodium cyclamate (E 952), Magnesium stearate, Talc, Silica, colloidal anhydrous, Raspberry flavor.

##### **What IronFol chewable tablets looks like and contents of the pack**

**IronFol** are black-brown and white speckled oblong chewable tablets, scored on both side.

10 chewable tablets are packed in a blister of Al/Al foil. Three blisters (30 tablets) and a patient information leaflet are put together in a carton box.

##### **Marketing Authorisation Holder and Manufacturer**

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