

**PACKAGE LEAFLET : INFORMATION FOR THE USER**

**FERRUM FOL 100 MG / 350 MICROGRAMS CHEWABLE TABLETS**

**Ferrum Fol 100 mg / 350 micrograms  
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.

**What is in this leaflet**

1. What Ferrum Fol chewable tablets is and what it is used for
2. What you need to know before you take Ferrum Fol chewable tablets
3. How to take Ferrum Fol chewable tablets
4. Possible side effects
5. How to store Ferrum Fol chewable tablets
6. Contents of the pack and other information

## 1. WHAT FERRUM FOL CHEWABLE TABLETS 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

## 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FERRUM FOL CHEWABLE TABLETS

**Do not take Ferrum Fol chewable tablets**  
if you are/have

- **allergic** to iron(III)-hydroxide polymaltose complex, folic acid or any of the other ingredients of this medicine listed in section 6
- an **iron overload** in the body
- **disturbed use of iron** by the body
- **reduced** number of **red blood cells** (anaemia), not caused by iron deficiency, such as due to
  - increased red blood cell breakdown
  - vitamin B12 deficiency

### Warnings and precautions

Talk to your doctor or pharmacist before taking Ferrum Fol chewable tablets if you have

- an **infection** or **tumour**
- a **vitamin B12 deficiency**  
The folic acid contained in Ferrum Fol chewable tablets may mask deficiencies of vitamin B12.

Dark discolouration of the faeces may occur during treatment with Ferrum Fol chewable tablets; however, this is harmless.

### Other medicines and Ferrum Fol chewable tablets

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 Ferrum Fol chewable tablets:

- injectable **iron** medicines  
Additional injectable, iron medicines are not recommended.
- **medicines to treat epilepsy**, particularly phenytoin  
Inform your doctor before taking Ferrum Fol chewable tablets.
- **chloramphenicol**: a medicine to treat bacterial infections

Your doctor will carefully monitor you if you take both medicines.

**Pregnancy and breast-feeding**

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

However, as a precaution: 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.

**Driving and using machines**

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

**3. HOW TO TAKE FERRUM FOL CHEWABLE TABLETS**

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

**The recommended dose**

- **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 (haemoglobin) value, continue with 1 tablet once daily until, 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 use**

Take Ferrum Fol chewable tablets during or immediately after a meal.  
The tablets can 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 Ferrum Fol chewable tablets than you should**

Contact your doctor or pharmacist if this occurs.

**If you forget to take Ferrum Fol chewable tablets**

Just take the next dose at the usual time. Do not take a double dose to compensate the forgotten dose.

**If you stop taking Ferrum Fol chewable tablets**

Do not discontinue sooner than recommended as this may reduce the success of therapy.

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:

**Very rare**, affects less than 1 user in 10,000

- abdominal pain
- constipation
- diarrhoea
- nausea, vomiting,
- indigestion
- skin rash
- itching

**Not known:** frequency cannot be estimated from the available data

- headache
- bloody stool
- tooth discolouration
- increased appetite

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

#### 5. HOW TO STORE FERRUM FOL CHEWABLE TABLETS

- Keep this medicine out of the sight and reach of children.
- Store below 25°C.
- Store in the original blister in order to protect from moisture.
- Do not use this medicine after the expiry date which is stated on the label and carton after “Exp.:”. The expiry date refers to the last day of that month.

#### 6. CONTENTS OF THE PACK AND OTHER INFORMATION

##### What Ferrum Fol contains

- 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

Ferrum Fol 100 mg / 350 micrograms  
chewable tablets Ireland

Vifor (International) Inc.

---

- The other ingredients are:
  - chocolate essence
  - cocoa
  - dextrates
  - microcrystalline cellulose
  - macrogol 6000
  - sodium cyclamate
  - talc
  - vanillin

**What Ferrum Fol looks like and contents of the pack**

Ferrum Fol chewable tablets are brown-white speckled, round and flat, with score line on one side.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Packages contain 10, 30 (3 packs of 10) or 500 (50 packs of 10) chewable tablets packed in aluminium strips.

Not all package sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

Vifor France SA

7-13, Bd Paul Emile Victor

92200 Neuilly-sur-Seine

France

Tel: +33 (0) 1 41 06 58 90

Fax: +33 (0) 1 41 06 58 99

**This leaflet was last revised in 06/2013.**