Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ferrum Fol 100mg / 350 micrograms Chewable Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 100 mg of Iron in the form of iron polymaltose and
350 micrograms of Folic Acid.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Brown-white speckled chewable, round and flat tablets with score-line on one side. This score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For prophylaxis of iron and folic acid deficiency during pregnancy.

4.2 Posology and method of administration

Adults only:

1 tablet a day throughout pregnancy.
Tablets may be chewed.

Route of administration:

Oral.

4.3 Contraindications

1. Use in patients with a known hypersensitivity to any of the active ingredients.

2. Use in patients with anaemia of undiagnosed aetiology.

4.4 Special warnings and precautions for use

This product should be used with caution in patients with haemochromatosis and haemolytic anaemias.

4.5 Interaction with other medicinal products and other forms of interaction

1. The absorption of iron salts is decreased in the presence of antacids.

2. Iron chelates with tetracyclines, absorption of both agents may be impaired.

4.6 Fertility, pregnancy and lactation

No information submitted.

4.7 Effects on ability to drive and use machines

No information submitted.

4.8 Undesirable effects

Side effects include nausea, diarrhoea, constipation may occur rarely.

4.9 Overdose

Symptoms of overdosage with iron salts include nausea and vomiting, abdominal pain, vomiting of blood and circulatory collapse. In severe cases, encephalopathy, acute hepatic necrosis and acute renal failure may develop after a latent period.
Treatment consists of gastric lavage followed by the introduction of 5 g desferrioxamine into the stomach. Serum iron levels should be monitored. In severe cases intravenous desferrioxamine should be administered together with supportive and symptomatic measures as required.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A haematinic with added folic acid.

5.2 Pharmacokinetic properties

A haematinic with added folic acid.

5.3 Preclinical safety data

No information submitted.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium cyclamate
Vanillin
Macrogol 6000
Essence of chocolate
Dextrates
Cocoa
Microcrystalline cellulose
Purified talc

6.2 Incompatibilities

Not applicable

6.3 Shelf life

5 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Double sided aluminium blisters contained in a carton.
Each blister strip contains 10 tablets.
Pack sizes: 10, 30 and 500 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Vifor France SA
123 rue Jules Guesde
F-92300 Levallois-Perret
France

8 MARKETING AUTHORISATION NUMBER

PA 949/2/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22 April 1992

Date of last renewal: 22 April 2007

10 DATE OF REVISION OF THE TEXT

July 2013