SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Ferrum Hausmann 100 mg chewable tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains 100 mg Iron as Iron(III)-hydroxide polymaltose complex.

For a full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

Chewable tablet

Circular, flat, brown and white speckled chewable tablets.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

- In the treatment of anaemia due to iron deficiency.
- Treatment and prophylactic therapy of iron deficiency during pregnancy. This product should only be used in pregnancy after the first thirteen weeks.

4.2. Posology and method of administration

Adults:
100 to 200 mg (1 chewable tablet to 2 chewable tablets) Iron daily depending on the severity of the anaemia.

Medical advice should be sought if symptoms do not improve after four weeks of use of this product as these symptoms may reflect an underlying disease process.

Route of administration:
Oral.

4.3. Contraindications

1. Use in patients with iron storage or assimilation diseases.
2. Use in patients with a known hypersensitivity to the active ingredient.
3. Use in individual with haemochromatosis and iron overload syndromes.

4.4. Special warnings and precautions for use

1. All medications containing iron should be kept out of reach of children.
2. The response to iron therapy should be regularly monitored.
3. The additional requirements for folic acid should be borne in mind when treatment with iron is carried out during pregnancy.
4. In cases of anaemia due to infection or malignancy, the substituted iron is stored in the reticulo-endothelial system, from which it is mobilized and utilised only after curing the primary disease.
5. Caution is advised in individuals with a family history of haemochromatosis or an iron overload syndrome. It should be noted that these conditions may be under diagnosed.
6. Overdose may be fatal.

4.5. Interaction with other medicinal products and other forms of interaction

Until now interactions have not been observed. Since the iron is complex-bound, ionic interaction with food components (phytin, oxalates, tannin etc.) and concomitant administration of medicaments (tetracyclines, antacids) are unlikely to occur.

The haemoccult test (selective for Hb) for the detection of occult blood is not impaired and therefore there is no need to interrupt iron therapy.

4.6. Fertility, pregnancy and lactation

This product should only be used in pregnancy after the first thirteen weeks.

Pregnancy category A:
Reproduction studies in animals did not show any foetal risk. Based on these animal studies there is no evidence of a risk during the first trimester and a negative influence on the foetus is unlikely. Controlled studies in pregnant women after the first trimester have not shown any undesirable effects on mother and neonates.

Breast milk naturally contains iron bound to lactoferrin. It is not known how much iron from the complex is passed into breast milk. The administration of Ferrum Hausmann Tablets is unlikely to cause undesirable effects to the nursed child.

During pregnancy and lactation Ferrum Hausmann Tablets should be used only after consulting a physician.

4.7. Effects on ability to drive and use machines

None stated.

4.8. Undesirable effects

Very rarely gastro-intestinal discomfort, vomiting, constipation or diarrhoea can occur.

A dark colouration of the stool is of no clinical significance.

4.9. Overdose

In cases of overdosage neither intoxication nor iron overload have been reported to date because the iron from the active substance Iron(III)-hydroxide polymaltose complex is not present in the gastro-intestinal tract as free iron and is not taken up by the organism by passive diffusion.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

The polynuclear Iron(III)-hydroxide cores are superficially surrounded by a number of non-covalently bound polymaltose molecules resulting in an overall complex molecular mass (Mw) of approximately 50 kD, which is so large that diffusion through the membrane of mucosa is about 40 times smaller than that of the hexaqua-iron(II) units. The complex is stable and does not release ionic iron under physiological conditions. The iron in the polynuclear cores is bound in a similar structure as in the case of physiologically occurring ferritin. Due to this similarity, only the iron(III) of the complex is absorbed by an active absorption process. By means of competitive ligand exchange, any iron binding protein in the gastro-intestinal fluid and on the surface of the epithelium take up iron(III). The absorbed iron is stored mainly in the liver, where it is bound to ferritin. Later in the bone marrow it is incorporated into haemoglobin. Iron(III)-hydroxide polymaltose complex has no prooxidative properties such as there are in iron(II) salts. The susceptibility of lipoproteins such as VLDL + LDL to oxidation is reduced.

Ferrum Hausmann chewable tablets do not cause teeth staining.

5.2. Pharmacokinetic properties

Studies using twin-isotope technique (^{55}Fe and ^{59}Fe) show that absorption of iron measured as haemoglobin in erythrocytes is inversely proportional to the dose given (the higher the dose, the lower the absorption). There is a statistically negative correlation between the extent of iron deficiency and the amount of iron absorbed (the higher the iron deficiency, the better the absorption). The highest absorption of iron is in the duodenum and jejunum. Iron which is not absorbed is excreted via the faeces. Excretion via the exfoliation of the epithelial cells of the gastro-intestinal tract and the skin as well as perspiration, bile and urine only amounts to approximately 1 mg of iron per day. For women, iron loss due to menstruation has also to be taken into account.

5.3. Preclinical safety data

No LD_{50} for Ferrum Hausmann could be determined in animal studies with white mice and rats up to an orally administered dose of 2,000 mg of iron per kilogram body weight.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Chocolate essence
Cocoa
Sodium cyclamate
Vanillin
Microcrystalline cellulose
Dextrates
Talc
Macrogol 6000

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

5 years.

6.4. Special precautions for storage

Do not store above 25°C. Store in the original package.

6.5. Nature and contents of containers

Double sided aluminium blisters contained in a carton.
Pack sizes: 30, 100, 250 and 500 tablets.

Not all pack sizes may be marketed.

6.6. Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Vifor France SA
7-13, Bd Paul Emile Victor
92200 Neuilly-sur-Seine
France

8. MARKETING AUTORISATION NUMBER

PA 949/3/2

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last revision: 10 January 2008

10. DATE OF REVISION OF THE TEXT