Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

Femifer syrup

2. Qualitative and quantitative composition

Each 5ml contains iron (III) hydroxide polymaltose complex
Equivalent to 50mg Elemental Iron and 0.5mg folic acid BP
Excipients with known effect
Sucrose
Sodium metabisulphite
Sorbitol
For a full list of excipients see section 6.1

3. Pharmaceutical form

Syrup
Dark brown coloured viscous syrupy liquid containing a flavoured base.

4. Clinical particulars

4.1 Therapeutic indications

Femifer syrup is used 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

Posology
Children 1-12 years: 5 -10ml (50mg-100mg) Iron daily
Adults: 10ml- 20ml (100mg – 200mg) Iron daily. Depending on the severity of the anaemia.
Method of administration
For oral administration.

4.3 Contraindications

Femifer is contraindicated in

- Iron overload e.g. hemochromatosis and hemosiderosis
- Disturbances in iron utilization e.g. lead anaemia, thalassemia
- Anaemia not caused by iron deficiency e.g. haemolytic anaemia
- Use in patients with a known hypersensitivity to the active ingredient.

4.4 Special warnings and precautions for use

- All medications containing iron should be kept out of reach of children.
- The response to iron therapy should be regularly monitored.
- The additional requirements for folic acid should be borne in mind when treatment with iron is carried out during pregnancy.
- In cases of anemia due to infection or malignancy, the substituted iron is stored in the reticulo-endothelial system, from which it is mobilized and utilized only after curing the primary disease

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 hemoccult 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 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. Controlled studies in pregnant women after the first trimester have not shown any undesirable effects on mother and neonates. There is no evidence of a risk during the first trimester and a negative influence on the foetus is unlikely.

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 syrup is unlikely to cause undesirable effects to the nursed child. During pregnancy and lactation Ferrum Hausmann syrup 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 diarrhea can occur.

Reporting of suspected adverse reactions:

Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS)

https://pv.pharmacyboardkenya.org

4.9 Overdose

In cases of overdosage neither intoxication nor iron overload have been reported to date because the iron from the active substance Ferric-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

ATC CLASS B03AD01

Mode of action

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 poly-nuclear 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 pro-oxidative properties such as there are in iron II) salts. The susceptibility of lipoproteins such as Very Low-Density Lipoprotein (VLDL) + Low Density Lipoprotein (LDL) to oxidation is reduced.

5.2 Pharmacokinetic properties

Studies using the twin-isotope technique (55 Fe and 59 Fe) show that absorption of iron measured as hemoglobin 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 amount 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

Non-clinical data reveals that no special hazard on humans based on conventional studies of repeated dose on toxicity or genotoxicity.

6. Pharmaceutical Particulars

6.1 List of Excipients

Sucrose
Sodium Methyl Hydroxy Benzoate
Sodium propyl Paraben
Bronopol
Di Sodium Edetate
Sodium Metabisulphite
Sodium citrate
Sorbitol solution 70% non-crystalline
Anhydrous citric acid
Xanthan Gum FNCS
Chocolate Flavour
Purified Water

6.2 Incompatibilities

None Applicable

6.3 Shelf-Life

24 months

6.4 Special Precautions for storage

Store between 30°C and away from the reach of children in tightly closed containers. Protect from light

6.5 Nature and Content of container

200ml Amber Glass bottle with cap and measuring device

6.6 Special precautions for disposal and other handling

No special requirements

7. Marketing Authorization Holder

BEKRA PHARMA UK LTD

8. Marketing Authorization Number

CTD9945

9. Date of first authorization/renewal of the authorization

08/11/2023

10. Date of revision of the text

12/05/2025