SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

1. NAME OF THE MEDICINALPRODUCT

Afrabron® Syrup

2. QUALITATIVE AND QUANTITATIVECOMPOSITION

Each 5ml contains Iron (iii) hydroxide polymaltose complex equivalent to elemental iron 50mg

{For a full list of excipients, see section 6.1}

3. PHARMACEUTICAL FORM

Syrup

Dark brown syrupy liquid.

4. Clinical particulars

4.1 Therapeutic indications

Afrabron® 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

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 individuals 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 mobilised and utilised 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 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 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 diarrhoea can occur.

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 Pharmacodynamics 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 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. Afrabron Syrup does not cause teeth staining.

5.2 Pharmacokinetic properties

Studies using the 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 amount to approximately 1 mg of iron per day. For women, iron loss due to menstruation has also to be taken into account.

6. PHARMACEUTICALPARTICULARS

6.1 List of excipients

Propylene glycol

Glycerol

Methyl paraben

Propyl paraben

EDTA Sodium

Liquid sorbitol 70%

Orange flavour

6.2 Incompatibilities

None known

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store between 30°C and away from the reach of children.

6.5 Nature and contents of container

200ml Amber Glass bottle with cap and measuring device

6.6 Special precautions for disposal

No special requirements

7 APPLICANT/MANUFACTURER

Afrab-Chem Limited,

22, Abimbola Street,

Isolo Ind. Estate,

Isolo, Lagos.

Nigeria**.**