Afrab-Chem Ltd

SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

1. NAME OF THE MEDICINAL PRODUCT

Afrabron® tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One tablet contains 100 mg elementary iron (as an iron III hydroxide polymaltose complex), and 1 mg folic acid. For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet
A round brown coated tablet.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Afrabron® tablet is used in the treatment of anaemia due to iron deficiency.
Treatment and prophylactic therapy of iron and folic acid deficiency during pregnancy and lactation.

4.2. Posology and Mode of Administration

Posology

Adults: 1- 2 tablets (100mg – 200mg) daily.
Depending on the severity of the anaemia.

Pediatric population
In a pediatric population AFRABRON Syrup may be used.

Mode of administration
Oral administration.
Afrabron tablet must be taken with or after meals.

4.3. Contraindications

Afrabron tablet is contraindicated:

In patients with iron storage or assimilation diseases.
In patients with a known hypersensitivity to the active ingredient.
Individuals with haemochromatosis and iron overload syndromes.

4.4. Special warning and precautions for use

- Anemia must always be treated under supervision by a physician.
- In iron deficiency anemia, with oral iron treatment the hemoglobin level is increased 1-2 g/dl in 2-4 weeks. Therefore a blood count is requested 2-4 weeks after the initiation of treatment.
- Patients, receiving repeated blood transfusions must be warned against iron overload, since each unit of whole blood contains approximately 250 milligrams of iron.
- Caution is necessary in patients with alcoholism and intestinal inflammation.
- Caution is necessary in patients with gastric ulcer.
- During administration of oral iron formulations, the color of stool may darken; this is normal and does not require any measures. I will not cause false positive results during tests for occult blood in stool. Therefore, there is no need to discontinue the treatment during this test.
- In anemia, associated with infection or malignancy, administered iron is stored in the reticuloendothelial system and is used with mobilization following the treatment of the primary disease.
- The tablet contains folic acid which can mask a deficiency in vitamin B12. Given the risk of irreversible neurological disorders, any possible deficiency in vitamin B12 in an anemic patient should be excluded before the start of the treatment (see section 4.3).
  Pediatric population Accidental administration of iron containing products can cause fatal toxicity in children below 6 years of age. In case of overdose the patients must promptly consult a physician or poison control center.

4.5 Interactions with other medicinal products and other forms of interactions

Since iron III ion in iron III hydroxide polymaltose complex is a complex ion, any ionic interaction with food or concomitant drugs (tetracyclines, antacids) is not expected. However, due to the possibility of an interaction with formulations containing calcium, at least 2 hours must be left between the administration of calcium and iron.

4.6.Fertility, Pregnancy and Lactation

Pregnancy category: A
This medicine is used as iron and folic acid supplement in pregnancy. Well-controlled epidemiological studies have shown that Iron III Hydroxide Polymaltose Complex has no adverse effects on the health of fetus/newborn or on pregnancy, so, Afrabron tablet may be used during pregnancy.

Lactation
This medicine is used as iron and folic acid supplement during lactation period. Iron is excreted into breast milk. This excretion does not change according to the existing iron level of mother and the quantity of iron taken with food. Therefore, the administration of iron formulations to lactating mother, does not yield an iron intoxication in the baby or the removal of existing iron deficiency in the baby. Afrabron tablet may be used during

lactation.

Fertility
No effects of Afrabron tablet on fertility have been determined.

4.7 Effects on the ability to drive and use machines

Afrabron tablet has no effects on the ability to drive vehicles or to operate machinery.

4.8. Undesirable effects

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

4.9 Overdose

In case of overdose, epigastric pain, diarrhea and vomiting may be seen, and in more severe cases metabolic acidosis, convulsions and coma. It has been reported that an excessive dose of folic acid could cause changes in the central nervous system (i.e., problems, changes in the rhythm of sleep, irritability, and hyperactivity), nausea, tension abdominal and flatulence. In case of overdose, the use of desferrioxamine (initially 1000 mg then 500 mg every 4 hours up to two doses IV), or calcium disodium EDTA (167 mg/m2 every 4 hours IM, in the form 1 mg/m2 IV in the form of 8-24 hour infusion or every 12 hours), are recommended (desferrioxamine has teratogenic effects).

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Iron in combination with folic acid- ferric oxide polymaltose complexes. ATC: B03AD04.
Afrabron tablet contains 100 mg of iron included as iron hydroxide polymaltose complex and 1 mg folic acid. This combination has been developed for the prevention and the treatment of iron and folic acid deficiencies.
Iron is found in all cells in body and has vital functions. It is present in the structure of enzymes (cytochrome oxidase, xanthine oxidase, succinic dehydrogenase), which play a role in energy transfer. In case of iron deficiency, the deficiency of these vital functions is seen. With the application of iron during pregnancy and lactation, the increasing iron requirement of the mother and infant are met and in case there is a deficiency, it is treated.
Folic Acid (Vitamin B9) is transformed to tetrahydrofolate in vivo and plays a role in various metabolic processes, including the synthesis of purine and pyrimidine nucleotides and related DNA copying and synthesis, producing new cells, and supporting nerve and immune system. Deficiencies in folic acid can be a serious problem leading to different health problems (poor immune function, chronic low energy, poor digestion, developmental problems during pregnancy and infancy, anemia, sores in the mouth and mood changes).

5.2. Pharmacokinetic properties

Iron
General characteristics
In the Iron hydroxide polymaltose complex, iron III hydroxide cores are surrounded by polymaltose molecules which are bonded superficially with non-covalent bonds. Therefore in

physiological environment ionic iron is not released and its effective absorption is provided.

Absorption
Iron is absorbed from intestines on duodenum and proximal jejunum. The absorption of the iron from intestines, varies from person to person and iron deficiency. Daily iron requirement of a normal adult is 0.5 to 1 mg. This value may increase to 1 to 2 mg per day in women during menstruation.

Distribution
70 % of total iron in body is stored in red blood cells in the form of hemoglobin, 10- 20 % stored in the form of ferritin and hemosiderin, and 10 % in myoglobin. Less than 1 % is found in trace quantities in cytochromes and other enzymes containing iron.

Elimination
Non-absorbed part of iron is excreted in feces.

Folic acid

General characteristics

Folic acid is a member of B group of vitamins. Folic acid is reduced to tetrahydrofolate in vivo. Tetrahydrofolate is the coenzyme of various metabolic processes, including purine and pyrimidine nucleotides and therefore DNA synthesis; it has a role in some amino-acid transformations, format formation and use. Deficiency results in megaloblastic anemia.

Absorption

Folic acid is rapidly absorbed from gastrointestinal tract, mainly from duodenum and jejunum and is transferred to portal circulation in unchanged form.

Distribution

In plasma and liver it is transformed to metabolically active form 5- methyltetrahydrofolate. Folate metabolites undergo enterohepatic circulation. Folate is excreted into breast milk.

Elimination
Surplus folate metabolites are excreted in urine without change.

5.3. Preclinical safety data

Iron III hydroxide polymaltose complex + folic acid combination has been used for many years in clinical practice as antianemic and its safety and efficacy is known.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Crospovidone, Magnesium stearate,Microcrystalline cellulose, Aerosil, Hydroxy propy methyl cellulose premix, Red iron oxide.

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

Blister pack of 3 x 10 tablets

6.6 Special precautions for disposal

No special requirements

7 APPLICANT/MANUFACTURER

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