EVANS BAROQUE LIMITED

SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC) GLOBAK SYRUP

1. NAME OF THE MEDICINAL PRODUCT

(Globak Syrup) Iron (III) Hydroxide Polymaltose and Folic Acid Syrup 50mg/5ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains:

Iron (III) Hydroxide Polymaltose complex

Eq.to Elemental Iron 50 mg

Folic Acid BP 1.0 mg

Flavoured Syrup base Q.S

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

3. PHARMACEUTICAL FORM

Dark brown colored, flavoured oral solution

4. Clinical particulars

4.1 Therapeutic indications

Prevention & treatment of all kind of iron deficiencies particularly iron deficiency anaemia & for the prevention of folic acid deficiency during pregnancy and lactation. The liquid formulation is especially for the prophylactic therapy of iron deficiency to cover the recommended daily dietary allowances for children adolescents & during pregnancy & lactation.

4.2 Posology and method ofadministration

Age group	Dose
Adult	5-10ml daily immediately after meals
Children (6-12 years)	5ml daily immediately after meals
Children (2-6 years)	2.5-5ml daily immediately after meals
Infants (5-10kg)	2.5ml once daily immediately after meals
Premature babies (less than 1500g)	3mg of elemental iron/kg body weight daily

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Method of administration

For oral administration

To be taken with or after food

4.3 Contraindications

- Use in patients with a known hypersensitivity to any of the active ingredients.
- Use in patients with anaemia of undiagnosed aetiology.
- Use in patients with iron storage or assimilation diseases.

4.4 Special warnings and precautions for use

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

4.5 Interaction with other medicinal products and other forms of interaction

- The absorption of iron salts is decreased in the presence of antacids.
- Iron chelates with tetracyclines, absorption of both agents may be impaired.

4.6 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. Continued administration may sometimes produce constipation. The faeces may be coloured black.

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 Pharmacodynamics properties

Pharmacotherapeutic Group: Iron preparations, iron in combination with folic acid.

ATC Code: B03AD04

Mechanism of action

Globak syrup is a combination preparation containing iron and folic acid for the treatment of iron deficiency before, during and after pregnancy (during lactation). Folic acid is an important vitamin for the development of the unborn child. Folic acid deficiency in the first weeks of pregnancy can lead to malformations in the child. The iron in Globak chewable tablets exist as iron (III)- hydroxide complex, where individual particles are embedded into a carbohydrate polymer (polymaltose). This prevents the iron from causing any harm in the gastrointestinal system.

The Iron (III) Hydroxide Polymaltose complex (IPC) is a water-soluble iron oxide, macromolecular complex of polynuclear iron (III) hydroxide that has distinct advantages over conventional iron preparations. As opposed to conventional iron salts that contain iron in ferrous form Iron polymaltose complex contains iron in ferric form, Ferrous releases an electron in the gastrointestinal tract before converting into ferric from. This electron is responsible for the formation of free radicals. Since iron is present in ferric form in iron polymaltose complex free radical do not form.

5.2 Pharmacokinetic properties

Studies using the twin-isotope technique (55Fe and 59Fe) 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.

5.3 Preclinical safety data

No information submitted.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Raw Material
Sucrose
Sorbitol 70% (non-crystallising)
Methyl parahydroxybenzoate
Propyl parahydroxybenzoate

Ethanol 96%
Aspartame
Purified Water
Chocolate Dry flavour

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store at a temperature not exceeding 30°C in a cool & dry place

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

200ml PET bottle in a carton along with a leaflet

6.6 Special precautions for disposal <and other handling>

No special requirements. Any unused product or waste material should be disposed of in accordance with local requirements.

7. MANUFACTURER

Evans Baroque Nigeria Limited

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Ogun State, Nigeria

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