National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) GLOBAK CHEWABLE TABLET

1. NAME OF THE MEDICINAL PRODUCT

(Globak Chewable Tablets) Iron (III) Hydroxide Polymaltose and Folic Acid Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each uncoated chewable tablet contains:

Iron (III) Hydroxide Polymaltose complex

Eq.to Elemental Iron 100 mg

Folic Acid BP 1.0 mg

Excipients Q.S

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

3. PHARMACEUTICAL FORM

Dark brown colored, round standard biconvex shape uncoated chewable tablet with on both side plain

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	Manifest deficiency	Latent Deficiency
Adults (Children>12 years of age) Nursing women	1-3 tablet daily	1 tablet daily
Pregnant women	1-3 tablet daily	1 tablet daily

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The daily dose can be divided into separate doses or can be taken at one time. Globak chewable tablets can be chewed or swallowed whole and should be taken during or immediately after a meal.

Method of administration

For oral administration

To be taken whole with liquid, preferably 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.

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.

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 chewable tablet 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 complexfree radical do not form.

5.2 Pharmacokinetic properties

A haematinic with added folic acid

5.3 Preclinical safety data

No information submitted.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Raw Material
Microcrystalline cellulose granules
Sodium citrate
Sodium chloride
Mannitol
Magnesium stearate
Aspartame
Purified Talc
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>

Alu/Alu containing 3 blisters of 10 tablets 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. APPLICANT

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