1. Name of the medicinal product

Zegem Chewable Tablet

2. Qualitative and quantitative composition

Each Tablet contains 50mg Iron Polymaltose, 100mcg Folic Acid.

3. Pharmaceutical form

Tablet, Chewable

4. Clinical particulars

4.1 Therapeutic indications

Zegem Chewable Tablets are indicated for the prevention and treatment of iron deficiency anaemia and folate deficiency in situations where a combined supplementation of iron and folic acid is necessary. The product is specifically indicated for use in:

1. Iron deficiency anaemia of various origins, including dietary deficiency, chronic blood loss, parasitic infestation, or malabsorption.
2. Increased physiological requirements, such as during:
3. Pregnancy and lactation
4. Periods of rapid growth, including adolescence and childhood
5. Prevention of neural tube defects and folate deficiency in women of child-bearing age, particularly in those who are planning pregnancy or are already pregnant.
6. Post-surgical states associated with risk of iron and folate depletion, including post-gastrectomy and bariatric surgery where indicated.
7. Zegem Chewable Tablets may also be used as supportive therapy in patients receiving treatment for conditions associated with chronic iron loss or reduced folate reserves where combined replacement is clinically justified.

4.2 Posology and method of administration

<u>Posology</u>

The dosage should be adjusted according to the degree of iron deficiency, age, body weight, and clinical response.

<u>Adults</u>

Therapeutic dose: 1–2 tablets daily.

Prophylactic dose: 1 tablet daily.

Pregnant and Lactating Women

Routine supplementation: 1 tablet daily.

Treatment of iron deficiency anaemia: 1–2 tablets daily, based on haemoglobin levels

and clinical assessment.

Children and Adolescents

Children 6–12 years: 1 tablet daily or as prescribed.

Adolescents (≥12 years): Same dosage as adults (1–2 tablets daily).

Use in children under 6 years is not recommended, unless specifically advised by a healthcare professional.

Elderly

Same adult dosing may be used; however, dose adjustment may be required in patients with gastrointestinal sensitivity or comorbidities. Monitoring of haemoglobin and ferritin is recommended.

Duration of Treatment

Treatment should be continued until haemoglobin levels normalize and iron stores are replenished.

Typically:

Therapeutic treatment: 3–6 months or as clinically required.

Prophylaxis in pregnancy: continued throughout pregnancy and the postpartum period, as recommended.

Method of Administration

For oral use only.

Tablets should be chewed thoroughly before swallowing.

May be taken with or after meals to reduce gastrointestinal discomfort.

If tolerated, taking the tablet between meals may enhance iron absorption.

Vitamin C-containing foods or beverages may aid absorption, while concomitant intake of tea, coffee, milk, or calcium supplements may reduce absorption and should be avoided within 2 hours of dosing.

4.3 Contraindications

Zegem Chewable Tablets are contraindicated in the following conditions:

1. Hypersensitivity to iron polymaltose complex, folic acid, or to any excipients in the formulation.

Iron overload disorders, including: Haemochromatosis and Haemosiderosis

2. Iron-loading anaemias such as thalassaemia major, sideroblastic anaemia, or other refractory anaemias, unless iron deficiency is also present.

3. Conditions associated with impaired iron utilisation, except where concurrent iron deficiency has been confirmed.

4. Active peptic ulcer disease or other severe gastrointestinal disorders where oral iron therapy is not advisable.

5. Megaloblastic anaemia not caused by folate deficiency, including vitamin B12 deficiency (e.g., pernicious anaemia), unless B12 supplementation is given concurrently.

6. Patients with known intolerance to iron salt preparations, unless benefits outweigh risks and therapy is closely monitored.

7. Use in children below 6 years of age is contraindicated unless prescribed and supervised by a healthcare professional due to risk of accidental iron toxicity.

4.4 Special warnings and precautions for use

Iron supplementation should only be used when iron deficiency or an increased requirement has been clinically confirmed. Routine administration in the absence of deficiency may lead to iron overload.

Caution is advised in the following situations:

- Gastrointestinal Effects:
  Oral iron therapy may cause gastrointestinal irritation, including nausea, abdominal discomfort, diarrhoea, or constipation. These effects are generally dose-related and may be minimized by administering the product with food.
- Risk of Iron Overload:
  Patients with disorders of iron metabolism, chronic transfusion therapy, or hereditary anemias (e.g., thalassemia, haemoglobinopathies) should be monitored due to the risk of iron accumulation.
- Monitoring Requirements:
  Periodic monitoring of haemoglobin, haematocrit, serum ferritin, or transferrin saturation is recommended to assess treatment response and prevent excessive dosing.
- Folate-Dependent Conditions:
  Folic acid may partially correct haematologic abnormalities in vitamin B12 deficiency (e.g., pernicious anaemia) without addressing neurological damage, which may progress. Patients with suspected B12 deficiency must be evaluated before initiating folate-containing therapy.
- Diabetic Patients:
  Iron polymaltose may contain carbohydrate components. Diabetic patients should be advised regarding possible effects on blood glucose monitoring.

- Concomitant Infections or Inflammation:
  In the presence of acute or chronic inflammatory conditions, iron absorption may be reduced. Treatment may be delayed until inflammation is controlled, unless clinically urgent.
- Use in Children:
  Accidental ingestion of iron-containing products may cause fatal poisoning in children. The product should be stored out of sight and reach of children.
- Dental and Oral Effects:
  Chewable formulations may temporarily stain teeth or dental appliances. Good oral hygiene is recommended following administration.

Patients should be informed that darkening of the stools may occur during therapy; this is harmless and related to unabsorbed iron.

4.5 Interaction with other medicinal products and other forms of interaction

Iron Polymaltose Complex

Due to its complex-bound structure, iron polymaltose is generally associated with fewer clinically significant interactions than ionic iron salts; however, interactions may still occur and should be considered.

- Medications That Reduce Gastric Acidity:
  Proton pump inhibitors (e.g., omeprazole), H2-receptor antagonists (e.g., ranitidine), and antacids (containing calcium, magnesium, or aluminium) may reduce iron absorption. A dosing separation of at least 2 hours is recommended.
- Tetracyclines and Quinolones:
  Co-administration with tetracycline antibiotics (e.g., doxycycline) or fluoroquinolones (e.g., ciprofloxacin, levofloxacin) may reduce the absorption of both medications. Dose separation of 2–4 hours is advised.
- Levothyroxine:
  Iron may decrease the absorption of levothyroxine, potentially leading to reduced therapeutic effect. A minimum interval of 4 hours between doses is recommended.
- Anticonvulsants:
  Iron may reduce the absorption of medications such as phenytoin and valproic acid. Monitoring of therapeutic drug levels may be required during co-administration.
- Penicillamine and Bisphosphonates:
  Concomitant intake may impair absorption of either agent; alternative timing of administration is advised (minimum 2-hour interval).

Folic Acid

- Antifolate Medicines:
  Folic acid may reduce the efficacy of antifolate agents such as methotrexate, pyrimethamine, and trimethoprim. Concomitant use should be clinically justified and monitored.
- Antiepileptic Drugs:
  Folic acid may reduce serum levels of antiepileptics such as phenytoin, phenobarbital, and

- primidone, potentially lowering seizure threshold. Dose adjustments and monitoring may be required.
- Sulfasalazine:
  Absorption and metabolism of folic acid may be decreased by sulfasalazine, potentially reducing therapeutic effect.

Food and Drink Interactions

- Milk, tea, coffee, high-fibre foods, and calcium-rich products may reduce iron absorption and should not be taken within 2 hours of the dose.

  Vitamin C (ascorbic acid) may enhance iron absorption and may be taken concurrently if clinically appropriate

  No interaction studies specific to this combination product have been conducted; however, caution should be exercised when administering other iron-containing medicinal products concurrently to avoid overdose.

4.6 Fertility, pregnancy and lactation

Pregnancy
Zegem Chewable Tablets may be used during pregnancy when iron and folic acid supplementation is clinically indicated. Iron requirements increase significantly during pregnancy, particularly in the second and third trimesters, and folic acid supplementation is recommended to support normal fetal development and reduce the risk of neural tube defects.
Clinical data and experience do not indicate an increased risk of congenital abnormalities when iron polymaltose complex and folic acid are used at recommended doses during pregnancy.
As with all iron-containing products, treatment should only be initiated following confirmation of iron deficiency or increased physiological requirement.

Breastfeeding
Zegem Chewable Tablets can be used during breastfeeding. Iron excretion into breast milk is physiologically regulated and is not significantly increased during maternal supplementation. Supplemental folic acid is also compatible with breastfeeding and contributes to maternal nutritional requirements.
No adverse effects on the breastfed infant are expected when the product is used within the recommended therapeutic range.

Fertility
There are no data suggesting that iron polymaltose or folic acid adversely affects male or female fertility. Adequate folate status is beneficial for reproductive health in both women and men.

As with all medicinal products, use during pregnancy and lactation should be based on a careful benefit–risk assessment and under the supervision of a healthcare professional.

4.7 Effects on ability to drive and use machines
Zegem Capsule has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Like all medicinal products, Zegem Chewable Tablets may cause adverse effects, although not everybody experiences them. Adverse reactions are generally mild and transient and are most commonly related to the gastrointestinal effects of oral iron.

Adverse reactions are classified according to frequency as follows:

- Very common (≥1/10)
- Common (≥1/100 to <1/10)
- Uncommon (≥1/1,000 to <1/100)
- Rare (≥1/10,000 to <1/1,000)
- Very rare (<1/10,000)
- Not known (cannot be estimated from available data)

Gastrointestinal Disorders

Frequency	Adverse Reaction
Common	Nausea, abdominal discomfort or pain, constipation, diarrhoea
Uncommon	Vomiting, dyspepsia, flatulence
Rare	Tooth or tongue staining (particularly with chewable formulations)

Darkening of stools is common and harmless and is associated with unabsorbed iron.

Immune System Disorders

Frequency	Adverse Reactions
Rare	Hypersensitivity reactions including rash, urticaria, or pruritus
Very Rare	Anaphylactoid reactions (reported primarily with parenteral iron; extremely unlikely with oral iron polymaltose)

Central Nervous System

Frequency	Adverse Reactions
Uncommon	

Metabolism and Nutrition Disorders

Frequency	Adverse Reactions
Not Known	Reduced absorption or interference with therapeutic efficacy of concomitant medicines (see section 4.5)

Paediatric Population

Gastrointestinal adverse effects may be more pronounced in children, though overall safety is comparable to adults when used at recommended doses.

4.9 Overdose

Iron Overdose

Acute overdose with iron-containing preparations, particularly in children, may result in serious toxicity and can be fatal. Although iron polymaltose complex has a lower risk of acute toxicity compared with ionic iron salts, clinically significant overdose may still occur.

Symptoms typically develop in stages:

1. Early Phase (within 1–6 hours):
    - Nausea, vomiting (which may be bloody), abdominal pain
    - Diarrhoea
    - Lethargy, pallor
    - Hypotension or tachycardia in severe cases
2. Latent Phase (6–24 hours):
    - Apparent clinical improvement may occur despite ongoing metabolic irritation and toxicity.
3. Systemic Toxic Phase (12–48 hours):
    - Metabolic acidosis
    - Shock, cardiovascular collapse
    - Hepatic dysfunction or failure
    - Coagulopathy
    - Renal impairment
4. Recovery or Late Complications (2–6 weeks):
    - Gastrointestinal scarring
    - Pyloric or intestinal strictures

Management of Iron Overdose

- Treatment should begin immediately based on clinical suspicion and not delayed pending laboratory confirmation.
- Emergency medical care is required, particularly in children.
- If ingestion is recent, administration of milk or antacids may reduce absorption.
- Gastric irrigation or whole-bowel lavage may be considered in significant ingestions.
- Deferoxamine or other iron-chelating therapy should be administered when indicated, based on iron levels and clinical status.
- Monitoring should include serum iron concentration, acid–base status, electrolytes, hepatic function tests, and renal function.

Folic Acid Overdose

Folic acid is generally well tolerated even at high doses. Excessive intake may lead to:

- Gastrointestinal discomfort

- Nausea
- Flatulence
- Sleep disturbances or irritability (rare)

Very high doses may mask symptoms of vitamin B12 deficiency and allow progression of neurological damage.

Management is supportive and symptomatic.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Iron preparations combined with folic acid. ATC code: B03AD.

Mechanism of Action

- Iron Polymaltose Complex:
  Iron polymaltose is a non-ionic, water-soluble complex of iron and polymaltose. It provides a source of bioavailable iron that is gradually released and absorbed in the gastrointestinal tract.
  - Once absorbed, iron is incorporated into hemoglobin, myoglobin, and iron-containing enzymes, thereby restoring iron-dependent physiological functions, including oxygen transport and energy metabolism.
  - The complexed form reduces the risk of free iron-mediated gastrointestinal irritation compared with ionic iron salts.
- Folic Acid (Vitamin B9):
  Folic acid is a water-soluble vitamin required for the synthesis of nucleic acids and erythropoiesis. It facilitates the production of DNA and RNA in rapidly dividing cells, particularly in bone marrow, and is critical for the maturation of erythrocytes.
  - Adequate folate status prevents megaloblastic anaemia and supports normal fetal development during pregnancy, including neural tube closure.

Pharmacodynamic Effects

- Corrects iron-deficiency anaemia by replenishing iron stores and increasing hemoglobin synthesis.
- Prevents or treats folate deficiency, thereby normalizing red blood cell morphology and preventing megaloblastic changes.
- Combined therapy is particularly effective in patients with concurrent iron and folate deficiencies, as both deficiencies commonly coexist in pregnancy, periods of rapid growth, or malnutrition.

Clinical Efficacy

- Clinical studies and extensive post-marketing experience indicate that iron polymaltose and folic acid supplementation increases hemoglobin levels and restores iron and folate stores over several weeks of therapy.
- The chewable tablet formulation improves compliance in children and adults who have difficulty swallowing conventional tablets.

5.2 Pharmacokinetic properties

Iron Polymaltose Complex

- Absorption:
  Iron from polymaltose complex is absorbed in the duodenum and upper jejunum. The complex releases iron gradually, minimizing free iron in the gastrointestinal lumen and improving gastrointestinal tolerability compared with ionic iron salts.
  - Absorption is inversely proportional to body iron stores; patients with iron deficiency absorb more efficiently.
  - Food, antacids, calcium, and high-fibre products may reduce absorption, while vitamin C may enhance it.
- Distribution:
  After absorption, iron binds to transferrin in plasma and is distributed to the bone marrow, liver, spleen, and other tissues where it is incorporated into hemoglobin, myoglobin, and iron-dependent enzymes.
- Metabolism:
  Iron is not metabolized; it is utilized for hemoglobin synthesis or stored as ferritin and hemosiderin.
- Elimination:
  Iron is eliminated minimally via sloughed intestinal mucosal cells, sweat, and minor amounts in urine. No renal excretion occurs in significant amounts.

Folic Acid

- Absorption:
  Folic acid is rapidly and almost completely absorbed from the small intestine following oral administration. Peak plasma concentrations are typically reached within 30–60 minutes after ingestion.
- Distribution:
  Circulates primarily as methylfolate bound to plasma proteins. It readily crosses the placenta and enters breast milk.
- Metabolism:
  Folic acid is reduced in the intestinal mucosa and liver to tetrahydrofolate derivatives, which serve as coenzymes in one-carbon transfer reactions critical for DNA and RNA synthesis.
- Elimination:
  Folic acid and its metabolites are excreted mainly in the urine. Excess folic acid is eliminated via renal excretion, with minimal accumulation at recommended doses.

Special Populations

- Elderly: Pharmacokinetics are generally not altered in elderly subjects when renal and hepatic function are normal.
- Renal or Hepatic Impairment: No specific dosage adjustment is usually necessary; monitoring may be prudent in severe impairment.
- Pediatric Population: Absorption and distribution are similar to adults; dosing should be weight-appropriate.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SMPC.

6 Pharmaceutical particulars

6.1 List of excipients

Folic Acid

Iron Polymaltose

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

None stated.

6.5 Nature and contents of container

Alu-PVC Blister Pack

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

7 Marketing authorisation holder

Zolon Healthcare Limited, Block A, Aswani Market Road, Isolo Lagos

Manufacturer: EMZOR PHARMACEUTCAL INDUSTRIES LIMITED, Flowergate Mixed Development Scheme,Km 1 Sagamu/Benin Expressway,Sagamu,Ogun State.

8 Marketing authorisation number(s)

A11-100374

9 Date of first authorisation/renewal of the authorisation

07/04/2022

10 Date of revision of the text

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