ELEZO®-BF

(Polysaccharide Iron Complex + Folic Acid + Vitamin B_{12})

WARNING:

Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or health care professional immediately.

1. NAME OF THE PRODUCT

ELEZO®-BF (Polysaccharide Iron Complex + Folic Acid + Vitamin B_{12}) 150mg/1mg/25mcg Capsule

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

ELEZO®-BF 150mg/1mg/25mcg Capsule

Each capsule contains:

Polysaccharide Iron Complex MS equivalent to Elemental Iron……150mg

Folic Acid USP……....1mg

Vitamin B_{12} (Cyanocobalamin) BP……..……..……25mcg

3. PHARMACEUTICAL FORM

Capsule

Appearance: Dark red opaque cap printed "**ELEZO-BF**" and reddish brown opaque body printed "ساجی" 3 times on them.

4. CLINICAL PARTICULARS

4.1. THERAPEUTIC INDICATIONS:

ELEZO®-BF is indicated for the prevention and treatment of iron deficiency anaemia and/or nutritional megaloblastic anaemia.

4.2. POSOLOGY AND METHOD OF ADMINISTRATION:

Posology:

Usual adult dosage is 1 capsule daily, or as directed by a physician.

Method of administration:

When possible, this medicine doses should be taken between meals.

4.3. CONTRAINDICATIONS:

Polysaccharide Iron Complex / Folic acid / Vitamin B12 capsule is contraindicated in patients with a known hypersensitivity to active or any of the excipients of this product. Hemochromatosis and hemosiderosis are contraindications to iron supplementation.

4.4. SPECIAL WARNINGS AND PRECAUTIONS FOR USE:

Folic acid alone is improper therapy in the treatment of pernicious anaemia and other megaloblastic anaemias where vitamin B_{12} is deficient.

General: Do not exceed recommended dose. The type of anaemia and the underlying cause or causes should be determined before starting Polysaccharide Iron Complex / Folic acid / Vitamin B_{12}. Since the anaemia may be a result of a systemic disturbance, such as recurrent blood loss, the underlying cause or causes should be corrected, if possible.

Folic Acid: Folic acid in doses above 0.1mg daily may obscure pernicious anaemia in that haematological remission can occur while neurological manifestations remain progressive. Pernicious anaemia should be excluded before using this product since folic acid may mask the symptoms of pernicious anaemia.

Paediatric use: Safety and effectiveness in paediatric patients have not been established.

Geriatric Use: Clinical studies on this product have not been performed in subjects aged 65 and over to determine whether elderly subjects respond differently from younger subjects. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

4.5. INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORM OF INTERACTIONS:

Alpha-Lipoic Acid: Iron preparations may decrease the absorption of Alpha-Lipoic Acid. Alpha-Lipoic Acid may decrease the absorption of Iron preparations. If alpha-lipoic acid is given 30 minutes before breakfast, then administer oral iron-containing products at lunch or dinner.

Antacids: May decrease the absorption of Iron preparations. If co-administered with antacids, monitor for decreased therapeutic effects of iron preparations.

Baloxavir Marboxil: Polyvalent cation containing products may decrease the serum concentration of Baloxavir Marboxil.

Bictegravir: Iron preparations may decrease the serum concentration of Bictegravir. Bictegravir, emtricitabine, and tenofovir alafenamide can be administered with iron preparations under fed conditions, but co-administration with or 2 hours after an iron preparation is not recommended under fasting conditions.

Bisphosphonate Derivatives: Polyvalent cation containing products may decrease the serum concentration of Bisphosphonate Derivatives. Avoid administration of oral medications containing polyvalent cations within: 2 hours before or after tiludronate/clodronate/etidronate; 60 minutes after oral ibandronate; or 30 minutes after alendronate/risedronate.

Cefdinir: Iron preparations may decrease the serum concentration of Cefdinir. Red-appearing, non-bloody stools may also develop due to the formation of an insoluble iron-cefdinir complex. Avoid concurrent cefdinir and oral iron when possible. Separate doses by at least 2 hours if combined. Iron-containing infant formulas do not appear alter cefdinir pharmacokinetics, but red-appearing, non-bloody stools may develop when combined.
Deferiprone: Polyvalent cation containing products may decrease the serum concentration of Deferiprone. Separate administration of deferiprone and oral medications or supplements that contain polyvalent cations by at least 4 hours.
Dimercaprol: May enhance the nephrotoxic effect of Iron preparations.
Dolutegravir: Iron preparations may decrease the serum concentration of Dolutegravir. Administer dolutegravir at least 2 hours before or 6 hours after oral iron. Administer dolutegravir/rilpivirine at least 4 hours before or 6 hours after oral iron. Alternatively, dolutegravir and oral iron can be taken together with food.
Eltrombopag: Polyvalent cation containing products may decrease the serum concentration of Eltrombopag. Administer eltrombopag at least 2 hours before or 4 hours after oral administration of any polyvalent cation containing product.
Elvitegravir: Polyvalent cation containing products may decrease the serum concentration of Elvitegravir. Administer elvitegravir 2 hours before or 6 hours after the administration of polyvalent cation containing products.
Entacapone: Iron preparations may decrease the serum concentration of Entacapone. Consider separating doses of the agents by 2 or more hours to minimize the effects of this interaction. Monitor for decreased therapeutic effects of levodopa during concomitant therapy, particularly if doses cannot be separated.
Ferric Hydroxide Polymaltose Complex: May decrease the serum concentration of Iron preparations. Specifically, the absorption of oral iron salts may be reduced. Do not administer intravenous (IV) ferric hydroxide polymaltose complex with other oral iron preparations. Therapy with oral iron preparations should begin 1 week after the last dose of IV ferric hydroxide polymaltose complex.
Fluorouracil Products: Folic Acid may enhance the adverse/toxic effect of Fluorouracil Products.
Fosphenytoin: Folic Acid may decrease the serum concentration of Fosphenytoin.
Green Tea: May decrease the serum concentration of Folic Acid.
Histamine H_2 Receptor Antagonists: May decrease the absorption of Iron preparations.
Levodopa: Iron preparations may decrease the serum concentration of Levodopa. Only applies to oral iron preparations. Consider separating doses of the agents by 2 or more hours to minimize the effects of this interaction. Monitor

for decreased therapeutic effects of levodopa during concomitant therapy, particularly if doses cannot be separated.

Levothyroxine: Iron preparations may decrease the serum concentration of Levothyroxine. Separate oral administration of iron preparations and levothyroxine by at least 4 hours. Separation of doses is not required with parenterally administered iron preparations or levothyroxine.

Methyldopa: Iron Preparations may decrease the serum concentration of Methyldopa. Consider separating doses of methyldopa and orally administered iron preparation by 2 or more hours. Monitor for decreased efficacy of methyldopa if an oral iron preparation is initiated/dose increase, or increased efficacy if discontinued/dose decreased.

Penicillamine: Polyvalent cation containing products may decrease the serum concentration of Penicillamine. Separate the administration of penicillamine and oral polyvalent cation containing products by at least 1 hour.

Phenobarbital: Folic Acid may decrease the serum concentration of Phenobarbital.

Phenytoin: Folic Acid may decrease the serum concentration of Phenytoin.

Phosphate Supplements: Iron preparations may decrease the absorption of Phosphate supplements. Administer oral phosphate supplements as far apart from the administration of an oral iron preparation as possible to minimize the significance of this interaction.

Primidone: Folic Acid may decrease the serum concentration of Primidone. Additionally, folic acid may decrease concentrations of active metabolites of primidone (e.g., phenobarbital).

Proton Pump Inhibitors: May decrease the absorption of Iron preparations.

Pyrimethamine: Folic Acid may diminish the therapeutic effect of Pyrimethamine. Folic acid doses greater than 2.5mg per day should be avoided due to the potential for sulfadoxine/pyrimethamine treatment failure. Consider limiting folic acid use to no more than 0.4mg per day for women of child-bearing age.

Quinolones: Iron preparations may decrease the serum concentration of Quinolones. Give oral quinolones at least several hours before (4 h for moxi- and sparfloxacin, 2 h for others) or after (8 h for moxi-, 6 h for cipro/dela-, 4 h for lome-, 3 h for gemi-, and 2 h for enox-, levo-, nor-, oflox-, peflox, or nalidixic acid) oral iron.

Raltegravir: Polyvalent cation containing products may decrease the serum concentration of Raltegravir. Administer raltegravir 2 hours before or 6 hours after administration of the polyvalent cations. Dose separation may not adequately minimize the significance of this interaction.

Raltitrexed: Folic Acid may diminish the therapeutic effect of Raltitrexed.

Sulfadoxine: Folic Acid may diminish the therapeutic effect of Sulfadoxine. Folic acid doses greater than 2.5mg per day should be avoided due to the

potential for Sulfadoxine/pyrimethamine treatment failure. Consider limiting folic acid use to no more than 0.4mg per day for women of child-bearing age.
Sulfasalazine: May decrease the serum concentration of Folic Acid.
Tetracyclines: May decrease the absorption of Iron preparations. Iron preparations may decrease the serum concentration of Tetracyclines. Avoid this combination if possible. Administer oral iron preparations at least 2 hours before, or 4 hours after, the dose of the oral tetracycline derivative. Monitor for decreased therapeutic effect of oral tetracycline derivatives.
Trientine: Polyvalent cation containing products may decrease the serum concentration of Trientine. Avoid concomitant administration of trientine and oral products that contain polyvalent cations. If oral iron supplements are required, separate the administration by 2 hours. If other oral polyvalent cations are needed, separate administration by 1 hour.

4.6. FERTILITY, PREGNANCY AND LACTATION:

Pregnancy: If pregnant or planning to become pregnant, the physician must be contacted before using or continuing the use of this product.
Breast-feeding: There are no data on the excretion of multivitamin with iron into human milk. Vitamins are naturally present in breast milk. Multivitamin with iron preparations is generally considered safe for the infant by most clinicians as long as doses do not exceed the recommended dietary allowance (RDA) for lactation designated for each active ingredient.

4.7. EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:

Not known.

4.8. UNDESIRABLE EFFECTS:

Adverse reactions with iron supplementation may include constipation, diarrhoea, nausea, vomiting, dark stools and abdominal pain. Adverse reactions with iron therapy are usually transient. Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

4.9. OVERDOSE:

The clinical course of acute iron overdosage can be variable. Initial symptoms may include abdominal pain, nausea, vomiting, diarrhoea, tarry stools, melaena, haematemesis, hypotension, tachycardia, metabolic acidosis, hyperglycaemia, dehydration, drowsiness, pallor, cyanosis, lassitude, seizures, shock and coma.

5. PHARMACOLOGICAL PROPERTIES

5.1. PHARMACODYNAMIC PROPERTIES:

Pharmacotherapeutic group: Antianaemic preparations, Iron preparation.
ATC Code: B03AE01.

Iron: Iron is an essential component in the formulation of haemoglobin. Adequate amounts of iron are necessary for effective erythropoiesis. Iron also serves as a cofactor of several enzymes, including cytochromes that are involved in electron transport.

Folic acid: Folic acid is required for nucleoprotein synthesis and the maintenance of normal erythropoiesis. Folic acid is converted in the liver and plasma to its metabolically active form, tetrahydrofolic acid by dihydrofolate reductase.

Vitamin B_{12}: Vitamin B_{12} is required for the maintenance of normal erythropoiesis, nucleoprotein and myelin synthesis, cell reproduction and normal growth. Intrinsic factor, a glycoprotein secreted by the gastric mucosa, is required for active absorption of vitamin B_{12} from the gastric tract.

5.2. PHARMACOKINETICS PROPERTIES:

Iron: 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 1mg of iron per day. For women, iron loss due to menstruation has also to be taken into account.

Folic Acid: Folic acid is rapidly absorbed from the gastrointestinal tract, mainly from the proximal part of the small intestine. Dietary folates are stated to have about half the bioavailability of crystalline folic acid. The naturally occurring folate polyglutamates are largely deconjugated and reduced by dihydrofolate reductase in the intestine to form 5-methyltetrahydrofolate (5MTHF). Folic acid given therapeutically enters the portal circulation largely unchanged, since it is a poor substrate for reduction by dihydrofolate reductases. 5MTHF from naturally occurring folate is extensively plasma bound. The principal storage site of folate is in the liver; it is also actively concentrated in the CSF. Folate is distributed into breast milk. Therapeutically given folic acid is converted into the metabolically active form 5MTHF in the plasma and liver. There is an enterohepatic circulation for folate. Folate metabolites are eliminated in the urine and folate in excess of body requirements is excreted unchanged in the urine. Folic acid is removed by haemodialysis.

Vitamin B_{12}: The absorption of cobalamins from the gut is dependent upon the glycoprotein intrinsic factor. Cobalamins are transported rapidly into the blood bound to protein, known as transcobalamins. Cobalamins are stored in the liver and excreted in the bile. They are known to cross the placenta.

5.3. PRECLINICAL SAFETY DATA:

No further relevant data.

6. PHARMACEUTICAL PARTICULARS

6.1. LIST OF EXCIPIENTS:

- Microcrystalline cellulose
- Dicalcium phosphate anhydrous
- Polyvinyl pyrrolidone
- Croscarmellose sodium
- Sodium lauryl sulfate
- Stearic acid
- Citric acid anhydrous
- Purified water
- Hard gelatin capsule

6.2. INCOMPATIBILITIES:

None stated.

6.3. SHELF LIFE:

See expiry on the pack.

6.4. SPECIAL PRECAUTIONS FOR STORAGE:

Do not store over 30°C, and protect from heat, light and moisture.
Improper storage may deteriorate the medicine.
Keep out of reach of children.

6.5. NATURE AND CONTENTS OF CONTAINER:

Alu/Alu blister, pack size is 10’s.

6.6. SPECIAL PRECAUTIONS FOR DISPOSAL OF A USED PRODUCT:

No any special requirements.

6.7. DRUG PRODUCT SPECIFICATIONS:

Innovator’s Specs.

7. REGISTRATION / MARKETING AUTHORISATION HOLDER

Manufactured by:
SAMI Pharmaceuticals (Pvt.) Ltd.
F-95, Off Hub River Road, S.I.T.E., Karachi-Pakistan
www.samipharma.com
Mfg Lic. No. 000072

8. REGISTRATION / MARKETING AUTHORISATION NUMBER(S)

126776

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

27th March, 2025

10. DATE OF REVISION OF THE TEXT

ایلی زو®- بی ایف کیپسول

(پولی سیکرائیڈ آئرن کمپلیکس + فولک ایسڈ + وٹامن بی ۱۲)

ہدایات:

خوراک ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

بچوں کی پہنچ سے دور رکھیں۔

دوا کو ۳۰ ڈگری سینٹی گریڈ سے زیادہ درجہ حرارت پر نہ رکھیں،

گرمی، روشنی اور نمی سے محفوظ رکھیں ورنہ دوا خراب ہو جائیگی۔