IRON + FOLIC ACID + VITAMIN B-COMPLEX

FORTIFER® - FA

TABLET

Anti-Anemia

FORMULATION

Each tablet contains:

Iron, elemental (as Ferrous Fumarate, 300 mg).....98.6 mg
Folic Acid.....500 mcg
Thiamine Mononitrate (Vitamin B_1).....5 mg
Pyridoxine Hydrochloride (Vitamin B_6).....5 mg
Cyanocobalamin (Vitamin B_{12}).....15 mcg

PRODUCT DESCRIPTION

This product is a red, capsule-shaped, sugar-coated tablet with glossy surface.

PHARMACODYNAMICS

Iron (as Ferrous Fumarate)

Iron is essential in the formation of healthy red blood cells. It is a component of two heme proteins: hemoglobin and myoglobin. Hemoglobin in red blood cells transports oxygen in the blood. Myoglobin in muscles facilitates the movement of oxygen in the muscle cells. Iron also acts as a cofactor of enzymes involved in energy metabolism. Cytochromes, for example, are heme-containing compounds critical to the electron transport chain. Iron also has immune-enhancing and cognition-enhancing properties.

Folic acid

Folic acid participates in several important metabolic processes in the body. It is essential for the normal growth and maintenance of all cells because it acts as a coenzyme required for normal DNA and RNA synthesis. Folic acid is vital for the reproduction of fetal cells; a deficiency affects normal cell division and protein synthesis, impairing growth. Folic acid, together with vitamin B_{12}, converts homocysteine to methionine thereby reducing blood levels of homocysteine and may help lower the risk of heart disease. Elevated plasma homocysteine or hyperhomocysteinemia may be a risk factor in the development of heart and blood vessel disease. Folic acid maintains nervous system integrity and intestinal tract functions. It is involved in the production of neurotransmitters such as serotonin, which regulate mood, sleep and appetite.

Thiamine Mononitrate (Vitamin B_1)

Thiamine plays an essential role as a cofactor in the key reactions in carbohydrate metabolism. It acts in two types of reactions upon conversion into the coenzyme thiamine pyrophosphate (TPP): oxidative decarboxylation and transketolation. These reactions are vital in carbohydrate metabolism, specifically in the citric acid cycle (Krebs cycle) and the pentose pathway. Thiamine assists in blood formation and nerve transmission. It is also involved in the conversion of the amino acid tryptophan to the vitamin niacin and the metabolism of the branched-chain amino acids leucine, isoleucine and valine.

Pyridoxine Hydrochloride (Vitamin B_6)

Pyridoxine is converted to its active forms, pyridoxal phosphate (PLP) and pyridoxamine phosphate (PMP). PLP facilitates more than 100 different enzymatic reactions that support protein metabolism, blood synthesis, carbohydrate metabolism, and neurotransmitter synthesis. It helps produce a number of neurotransmitters including serotonin, gamma amino butyric acid (GABA), dopamine, and epinephrine. Pyridoxine supports the synthesis of white blood cells of the immune system and is crucial for the synthesis of the hemoglobin rings of red blood cells, which carry oxygen to hemoglobin. Inadequate vitamin B_6 disturbs the binding of oxygen to hemoglobin, causing microcytic hypochromic anemia. In this type of anemia, red blood cells are smaller than normal and also lack sufficient hemoglobin to carry oxygen.

Cyanocobalamin (Vitamin B_{12})

Cyanocobalamin plays a key role in folate metabolism by transferring a methyl group from the folate coenzyme tetrahydrofolic acid (THFA), which is important in many metabolic pathways. Cyanocobalamin is required in the synthesis of myelin, the white sheath of lipoprotein that surrounds many nerve fibers. During cyanocobalamin deficiency, progressive demyelination of nerve fibers occurs, leading to a variety of neurological symptoms. Cyanocobalamin is involved in biochemical processes essential for DNA synthesis. A cellular deficiency of vitamin B_{12} can impair DNA synthesis for growth and division of cells. The lack of DNA affects red blood cells which rapidly turn over every 120 days. When red blood cell precursors in the bone marrow are not able to form new DNA, they cannot divide normally to become red blood cells. As these precursor cells continue to synthesize protein and other cell components, they grow into large, fragile, immature cells which displace red blood cells and cause megaloblastic anemia.

PHARMACOKINETICS

Iron (as Ferrous Fumarate)

Iron is irregularly and incompletely absorbed from the gastrointestinal tract, the main sites of absorption being the duodenum and jejunum. Absorption is aided by the acid secretion of the stomach and by some dietary acids. Absorption is also increased in conditions of iron deficiency or in the fasting state but is decreased if the body stores are overloaded. Only 5 to 15% of the iron ingested in food is usually absorbed. About 33% of iron is absorbed from every 100 mg of iron from ferrous fumarate. After absorption, the majority of iron is bound to transferrin and transported to the bone marrow where it is incorporated to hemoglobin. In the absence of bleeding (including menstruation), only a small amount of iron is lost daily. The majority of losses occur through the desquamation of the cells of the gastrointestinal tract and smaller amounts are lost through the skin and the urine.

Folic acid

Folic acid is absorbed rapidly from the gastrointestinal tract after oral administration; the nutrient is absorbed mainly from the proximal portion of the small intestine. Folic acid is distributed in the plasma and extracellular fluid. Folic acid is bound weakly to albumin in plasma. Folic acid enters breast milk which may be beneficial to the infant. Folic acid is excreted in the urine as folic acid cleavage products. Intact folic acid enters the glomerulus and is reabsorbed into the proximal renal tubule. Very little intact folic acid is excreted in the urine. Folic acid is excreted in the bile and much of it is reabsorbed via the enterohepatic circulation.

Thiamine Mononitrate (Vitamin B_1)

Thiamine is readily absorbed in the jejunum by active transport and passive diffusion mechanisms. It is transported by the portal and systemic circulations to the liver and to the various tissues in the body. Thiamine is metabolized in the liver and excreted in the urine.

Pyridoxine Hydrochloride (Vitamin B_6)

Pyridoxine is readily absorbed from the jejunum after oral administration. It is stored mainly in the liver and lesser amount, in the muscle and brain. Pyridoxine is converted to the active forms pyridoxal phosphate and pyridoxamine phosphate. In the liver, pyridoxal is oxidized to 4-pyridoxic acid which is excreted in the urine.

Cyanocobalamin (Vitamin B_{12})

Cyanocobalamin binds to intrinsic factor, a glycoprotein produced by the gastric mucosa, and is then actively absorbed from the gastrointestinal tract. Absorption from the gastrointestinal tract can also occur by passive diffusion; little of the vitamin present is absorbed in this manner although the process becomes increasingly important with larger amounts such as those used therapeutically. Cyanocobalamin is extensively bound to transcobalamin which is involved in the rapid transport of the cobalamins to tissues. Cyanocobalamin is stored in the liver, excreted in the bile, and undergoes extensive enterohepatic recycling; part of the administered dose is excreted in the urine.

INDICATIONS

- For the prevention and treatment of iron deficiency anemia and folic acid deficiency in pregnant women
- For the prevention of neural tube defects in infants

DOSAGE AND ADMINISTRATION

Orally, one tablet daily. For severe anemia, the dose is one tablet twice daily. Or, as prescribed by a physician.

CONTRAINDICATIONS

- Hypersensitivity to any component of the product
- Patients with primary hemochromatosis, peptic ulcer, regional enteritis, or ulcerative colitis
- Patients receiving parenteral iron or blood transfusions to avoid iron overload

WARNINGS AND PRECAUTIONS

- This medicine should not be used to treat hemolytic anemias unless an iron deficiency state also exists.
- Therapeutic iron doses should not be administered longer than six months except under the supervision of a physician.

INTERACTIONS WITH OTHER MEDICAMENTS

- Antacids should be taken at least one hour before taking this medicine to avoid decreased iron absorption.
- Tetracyclines should be taken at least one hour before or three hours after taking this medicine to avoid reduced absorption of both drugs.
- Quinolones (e.g., ciprofloxacin, norfloxacin, ofloxacin, levofloxacin) should be taken at least two hours before taking this medicine since iron may cause decreased concentrations of quinolones.
- Concomitant intake of chloramphenicol and iron salts results in delayed responses to iron therapy especially in patients with iron deficiency anemia.
- Carbidopa, levodopa, methyldopa and penicillamine should be taken at least two hours before taking this medicine since iron may decrease absorption and reduce the bioavailability of these drugs.

UNDESIRABLE EFFECTS

- Gastrointestinal side effects such as nausea, vomiting, bloating, and upper abdominal discomfort are seen with high iron doses (usually greater than 120 mg elemental iron per day)
- May cause temporary staining of teeth
- Stools may appear darker in color.

OVERDOSE AND TREATMENT

Symptoms of acute iron overdosage can be divided into four stages:
Stage I – occurs up to six hours after ingestion, the principal symptoms are vomiting and diarrhea. Other symptoms include hypertension, tachycardia and central nervous system depression ranging from lethargy to coma

Stage II – may occur 6 to 24 hours after ingestion and is characterized by a temporary remission or signs of overdosage are decreased

Stage III – gastrointestinal symptoms recur accompanied by shock, metabolic acidosis, coma, liver necrosis, jaundice, hypoglycemia, kidney failure, and pulmonary edema

Stage IV – occur several weeks after ingestion and is characterized by gastrointestinal obstruction and liver damage

Gastric lavage with 1% sodium bicarbonate or induction of vomiting should be undertaken. Deferoxamine has also been used as additive to gastric lavage solutions to chelate elemental iron in the gastrointestinal tract.

Supportive treatment such as suction and maintenance of airway, correction of acidosis, and control of shock and dehydration should be administered as required when a potentially lethal dose of iron (e.g., 5,400 – 10,000 mg elemental iron per day) has been ingested.

STORAGE CONDITIONS

Store at temperatures not exceeding 30°C.
Keep the product out of reach and sight of children.

CAUTION

Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

AVAILABILITY

Box of 100 tablets (in flex foil)

For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph **AND** Unilab at (+632) 858-1000 or productsafety@unilab.com.ph. By reporting undesirable effects, you can help provide more information on the safety of this medicine.

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