Iron + Vitamin B-Complex + Folic Acid

Hemarate® FA

Tablet
Anti-anemia
(Iron-Multivitamins Combination)

FORMULATION
Each tablet contains:
Iron, elemental (as Ferrous Sulfate, 187 mg) ..... 60 mg
Folic Acid ..... 600 mcg
Pyridoxine Hydrochloride (Vitamin B6) ..... 20 mg
Cyanocobalamin (Vitamin B12) ..... 25 mcg

PRODUCT DESCRIPTION
Hemarate® FA is a round, pink, biconvex tablet bisected on one side and plain on the other side.

WHAT IS IN THE MEDICINE?
Hemarate® FA tablet contains iron, folic acid, vitamins B_6 and B_{12}. These nutrients are essential for healthy blood, synthesis of hemoglobin (an oxygen containing protein which gives blood its red color) and to prevent and treat iron deficiency anemia (IDA).

Folic acid, vitamins B_6 and B_{12} are also required in the metabolism of homocysteine to prevent its accumulation in the blood. Elevated blood homocysteine or hyperhomocysteinemia may be a risk factor in the development of cardiovascular disease. The effects of homocysteine in pregnancy include preeclampsia and adverse pregnancy outcomes. Hyperhomocysteinemia has also been reported to result in neural tube defects (NTDs).

Iron, folic acid, vitamins B_6 and B_{12} have the following functions:

NUTRIENTS	FUNCTIONS
Iron	• Iron is essential in the formation of blood, transport and storage of oxygen and as a cofactor required for the proper functioning of cells. • Iron 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. • Pregnant women are at high risk of iron deficiency because of increased iron needs necessary to replace normal losses, to facilitate growth of the baby in the womb, to cope with the demands of pregnancy, and to replace unusual losses, such as heavy bleeding during delivery. • Lack of iron results to iron deficiency anemia - a disease characterized by insufficient or defective red blood cells, or both. The physical symptoms most frequently associated with iron deficiency anemia are pallor, fatigue, dyspnea (difficulty in breathing), palpitations and reduced capacity to work.
Folic acid	• Folic acid is involved in a number of single carbon transfer reactions, especially in the synthesis of purines and pyrimidines (and hence the synthesis of DNA), glycine and methionine. • Folic acid is involved in some amino acid conversions and the formation and utilization of formate. • Folic acid is required for the prevention of NTDs in infants. NTDs are malformations of the baby's brain and/or spinal cord which can be prevented by adequate folic acid intake particularly during the very early stages of pregnancy. • Folic acid is an antihomocysteine nutrient that helps reduce plasma homocysteine levels. It is an important substrate in the remethylation of homocysteine to methionine. Elevated blood homocysteine or hyperhomocysteinemia may be a risk factor in the development of cardiovascular disease.
Folic Acid	• Folic acid deficiency may be caused by inadequate folic acid consumption and absorption, altered folic acid metabolism, excessive folic acid excretion and drugs such as sodium bicarbonate, ibuprofen, aspirin, fluoroquinolones, phenobarbital and metformin. • Folic acid deficiency leads to anemia, low platelet count, impaired cell division, NTDs and adverse pregnancy outcomes such as prematurity and very low birth weight.
Vitamin B6	• Vitamin B_6 acts as a cofactor for enzymes which are involved in more than 100 reactions that affect protein, lipid and carbohydrate metabolism. • It is also involved in the synthesis of several neurotransmitters, the metabolism of several vitamins (e.g. the conversion of tryptophan to niacin), hemoglobin and sphingosine formation. • Vitamin B_6 supports the synthesis of the white blood cells of the immune system and is crucial for the synthesis of the red blood cell's hemoglobin rings, which carry oxygen to hemoglobin. • Vitamins B_6 is an antihomocysteine nutrient that helps lower plasma homocysteine levels by converting homocysteine to cysteine. • Deficiency of vitamin B_6 may cause microcytic hypochromic anemia and may lead to the accumulation of homocysteine in the blood which will lead to hyperhomocysteinemia.
Vitamin B12	• Vitamin B_{12} is involved in the recycling of folate coenzymes and the degradation of valine. • It is also required for nerve myelination, cell replication, and hematopoiesis and DNA synthesis. • Vitamin B_{12} is an antihomocysteine nutrient that helps reduce plasma homocysteine levels. It acts as a cofactor for the folate-dependent methionine synthase mediating the conversion of homocysteine to the amino acid methionine. • Deficiency of vitamin B_{12} may lead to the accumulation of homocysteine in the blood which will lead to hyperhomocysteinemia.

STRENGTH OF THE MEDICINE
Please see formulation

WHAT IS THE MEDICINE USED FOR?
For the prevention and treatment of iron deficiency anemia, folate deficiency and for the lowering of plasma homocysteine.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THE MEDICINE?
Orally, one tablet daily as soon as pregnancy is detected.
Or, as directed by a doctor.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?
• If you are allergic to any ingredient in the product
• Iron supplement should be avoided in conditions associated with iron overload (e.g., hemochromatosis, hemosiderosis, thalassemia).

UNDESIRABLE EFFECTS
The amount of nutrients in this product is relatively nontoxic and is usually well tolerated. However, undesirable effects may occur, particularly when the nutrients are used at high doses (e.g., concomitant use of other multivitamin-mineral supplements), see also ***Signs and Symptoms of Overdosage***.

Iron
The most common undesirable effects of iron are gastrointestinal (GI) problems, including nausea, vomiting, bloating, abdominal discomfort/epigastric pain, black stools, diarrhea, constipation and anorexia.

Nervous system disorders: Metallic taste
Gastrointestinal disorders: flatulence, gastrointestinal irritation, heartburn, stomach discomfort
Injury, poisoning and procedural complications: Long-term administration of large amounts of iron may cause hemosiderosis clinically resembling hemochromatosis, which is a genetic condition characterized by excessive iron absorption, excess tissue iron stores, and potential tissue injury.

Vitamin B6
Although vitamin B6 is generally considered to be relatively nontoxic, adverse neurologic effects have been reported following chronic administration of large pyridoxine dosages, e.g., more than 200 mg daily.

Psychiatric disorders: Sleepiness
Nervous system disorders: Headache, paresthesia (tingling, prickling, or burning sensation),
Gastrointestinal disorders: Nausea
Investigations: Decreased serum folic acid concentrations, increased serum aspartate aminotransferase (AST, a liver enzyme)

WHAT OTHER MEDICINE OR FOODS SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?
Iron
• Cefdinir; bisphosphonates; carbidopa/levodopa; entacapone; fluoroquinolones; levodopa; levothyroxine; methyldopa; mycophenolate mofetil; penicillamine; and tetracyclines: Iron may reduce the absorption of these drugs.

Tell your doctor about other medicines you are taking including supplements and herbal products.

WHAT SHOULD YOU DO IF YOU MISS A DOSE?
If you miss a dose, just take the next dose and the subsequent doses at the usual recommended schedule, i.e., once a day.

Do not double the dose unless recommended by a doctor.

SIGNS AND SYMPTOMS OF OVERDOSAGE
Iron
Acute iron overdosage (e.g., intake of ≥ 1,500 mg elemental iron for a 50 kg adult) 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 hypotension, tachycardia (rapid heartbeat) and central nervous system depression ranging from lethargy (sleepiness) to coma (state of unconsciousness).

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 - GI symptoms recur accompanied by shock, metabolic acidosis (increased acid in the blood), coma, hepatic necrosis (death of liver tissue), jaundice (yellowish color of the skin, eyes and other tissues), hypoglycemia (low blood sugar), kidney failure, and pulmonary edema (fluid in the lungs).

Stage IV - Occurs several weeks after ingestion and is characterized by GI obstruction (blockage) and liver damage.

Vitamin B6
Long term administration (i.e., 2 months or longer) of large (megadose) dosages (e.g., 2 g or more daily) of pyridoxine can cause sensory neuropathy or neuronopathy syndromes.
Other side effects reported with megadoses of pyridoxine include peripheral neuropathy, unsteady gait (manner of walking), loss of limb reflexes/numbness and tingling in feet and hands, hyperesthesia (increased physical sensitivity), muscle weakness, impaired or absent tendon reflexes; bone pain, headache, dizziness, sleepiness, nausea, upset stomach, breast tenderness, photosensitivity on sun exposure, and exacerbation of acne.

WHAT TO DO WHEN YOU HAVE USED MORE THAN THE RECOMMENDED DOSAGE?
If you have taken more than the recommended dosage, consult a doctor or contact a poison control center immediately.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE
• Iron supplement should be used with extreme caution in those with chronic liver failure, alcoholic cirrhosis, chronic alcoholism, and pancreatic insufficiency.
• Iron should be used cautiously in those with a history of gastritis, peptic ulcer, and GI bleeding.
• Individuals with an active or suspected infection should generally avoid iron supplements.
• A moderate increase in iron stores has been associated with an increased risk of ischemic heart disease and cancer.
• Do not take more than the recommended dose. If you are taking other supplements, read the label, since those supplements may contain the same ingredients as this product.
• Do not use after the expiry date on the label.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?
• If any undesirable effect occurs

HOW SHOULD YOU KEEP THIS MEDICINE?
• Since accidental overdosage of iron-containing preparations is a leading cause of fatal poisoning in children younger than 6 years old, it is advisable to **keep this product out of sight and reach of children.**
• Store at temperatures not exceeding 30°C.
• Protect from light.

ADVERSE DRUG REACTION REPORTING STATEMENT
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.

AVAILABILITY
Aluminum Foil Strip x 10's (Box of 100's)

DATE OF REVISION OF THE PACKAGE INSERT: September 2018

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Manufactured by:
AMHERST LABORATORIES, INC.
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