IRON + VITAMIN B COMPLEX

Ferlin®Syrup (Oral Drops)
Each mL syrup (oral drops) contains:
Iron, elemental (as Ferrous Sulfate, 74.64 mg) ..... 15 mg
Thiamine Hydrochloride (Vitamin B_1) ..... 10 mg
Pyridoxine Hydrochloride (Vitamin B_6) ..... 5 mg
Cyanocobalamin (Vitamin B_{12}) ..... 10 mcg

Ferlin®Syrup
Each 5 mL (1 teaspoonful) syrup contains:
Iron, elemental (as Ferrous Sulfate, 149.34 mg) ..... 30 mg
Thiamine Hydrochloride (Vitamin B_1) ..... 10 mg
Pyridoxine Hydrochloride (Vitamin B_6) ..... 10 mg
Cyanocobalamin (Vitamin B_{12}) ..... 50 mcg

FERLIN®
Hematinic

***Syrup (Oral Drops)**
***Syrup**

PRODUCT DESCRIPTION
Ferlin®Syrup (Oral Drops) is a brown-colored, cherry-orange flavored syrup.
Ferlin®Syrup is a brown-colored, fruit-flavored syrup.

WHAT IS IN THE MEDICINE?
This medicine contains iron and vitamins B_1, 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).
Inadequate dietary intake of iron resulting in IDA is one the most common nutritional disorders among infants and children. This is due to the higher iron requirements in these age groups to facilitate growth which is accompanied by an increase in body weight and blood volume. Iron deficiency anemia is associated with decreased physical growth, impaired immune system and reduced brain (behavioral and cognitive) development.

STRENGTH OF THE MEDICINE
Please see Formulation.

WHAT IS THIS MEDICINE USED FOR?
This medicine is used for the prevention and treatment of iron deficiency anemia in infants and children.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?
Dose is based on elemental iron.
Consultation with a doctor/pediatrician is highly recommended.

Supplemental Dose (Prophylaxis to prevent iron deficiency anemia):

Full-Term Infants	1 mg/kg body weight per day up to a maximum of 15 mg/day. To start no later than 4 to 6 months of age and to continue up to 2 years of age.
Preterm Infants or Low Birth Weight Infants	2 mg/kg body weight per day up to a maximum of 15 mg/day. To start no later than 2 months of age and to continue up to 2 years of age.
Children 2 to 12 years old	1 to 2 mg/kg body weight per day up to a maximum of 30 mg/day. Duration of treatment is usually 3 months, or as directed by a doctor.

Therapeutic Dose (To treat iron deficiency anemia):
Children: 3 mg/kg body weight per day up to a maximum of 60 mg/day
- Iron is best taken on an empty stomach, but may be taken with or after meals, if necessary, to reduce the possibility of stomach upsets.
- If the patient is unable to tolerate once a day dosing, iron can be given in 3 divided doses.
- Duration of treatment depends on the cause and severity of iron deficiency but in general, 3 months of iron therapy is required to reverse uncomplicated iron deficiency anemia.

Iron + Vitamin B-Complex (Ferlin®) Syrup (Oral Drops) Recommended Oral Dose

Age Group	Supplemental Dose (based on 1 mg/kg body weight/day)	Therapeutic Dose (based on 3 mg/kg body weight/day)	
	To be given once a day	To be given once a day	To be given 3 times a day
4 to 6 months	0.5 mL	1.5 mL	0.5 mL
7 to 12 months	0.5 to 0.75 mL	2.25 to 3 mL	0.75 to 1 mL
1 to 2 years	0.75 to 1 mL	3 mL	1 mL
	Or, as directed by a doctor.		

Iron + Vitamin B-Complex (Ferlin®) Syrup Recommended Oral Dose

Age Group	Supplemental Dose (based on 1 mg/kg body weight/day)	Therapeutic Dose (based on 3 mg/kg body weight/day)	
	To be given once a day	To be given once a day	To be given 3 times a day
2 to 6 years	2.5 mL (½ teaspoonful)	7.5 mL (1½ teaspoonsful)	2.5 mL (½ teaspoonful)
7 to 12 years	2.5 to 5 mL (½ to 1 teaspoonful)	7.5 to 10 mL (1½ to 2 teaspoonsful)	2.5 to 3.5 mL
	Or, as directed by a doctor.		

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?
- If the patient has allergy to any ingredient in the product
- In conditions associated with iron overload (e.g., hemochromatosis, hemosiderosis, thalassemia)
- In patients receiving parenteral iron or repeated blood transfusions
- Oral iron may aggravate severe acute inflammatory intestinal disease and is ineffective in patients with extensive small intestinal disease, e.g., celiac sprue.
- Since the product contains cyanocobalamin, it is contraindicated in patients who have experienced hypersensitivity reactions to cobalt; and in those with early Leber's disease (hereditary optic nerve atrophy) or tobacco amblyopia, since rapid wasting of the optic nerve has been reported following its administration to these patients.

UNDESIRABLE EFFECTS
- **Iron:** Gastrointestinal side effects such as epigastric pain/discomfort, nausea, diarrhea, or constipation are usually seen with doses of 60 mg or more elemental iron per day; constipation may lead to fecal impaction, particularly in the elderly; anorexia, black/dark stools, bloating, GI irritation, heartburn, metallic taste, vomiting may also occur, as well as exacerbation of diarrhea in patients with inflammatory bowel disease

  Liquid iron preparations may cause temporary staining of teeth.

  Administration of iron preparations to premature infants who normally have low serum vitamin E concentrations may cause increased red cell hemolysis and hemolytic anemia. Vitamin E deficiency should also be corrected, if possible.

  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 B_1:** There appear to be no toxic effects (except possibly gastric upset) with high dose oral thiamine. It is well tolerated even at doses up to 200 mg daily or higher.
- **Vitamin B_6:** Although vitamin B_6 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. Nausea, headache, paresthesia (tingling, prickling, or burning sensation), sleepiness, increased serum aspartate aminotransferase (AST, a liver enzyme), and decreased serum folic acid concentrations have been reported. Allergic reactions have been reported occasionally in patients receiving the vitamin.
- **Vitamin B_{12}:** Occasional diarrhea and skin itching; signs of polycythemia vera may be unmasked; megadoses may exacerbate acne

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?
The following interactions should be considered before giving this medicine.

Iron
- Ascorbic acid may increase the absorption of iron.
- Antacids and other GI drugs (e.g., H_2-receptor antagonists; proton pump inhibitors) should be taken at least one hour before taking this medicine to avoid decreased iron absorption. Calcium, magnesium, and zinc may also decrease the absorption of iron.
- Concomitant intake of chloramphenicol and iron salts results in delayed responses to iron therapy especially in patients with iron deficiency anemia.
- Bisphosphonates; carbidopa/levodopa; cefdinir; entacapone; fluoroquinolones; methyldopa; mycophenolate mofetil; penicillamine; thyroid agents (e.g., thyroxine); and tetracyclines should be taken at least two hours before taking this medicine since iron may decrease absorption and reduce the bioavailability and clinical effect of these drugs.
- Dairy foods, eggs, and caffeine-containing beverages may decrease the absorption of iron.

Vitamin B6
- Effects of levodopa are reversed by pyridoxine (even doses as low as 5 mg daily); vitamin B6 supplements should be avoided.
- Vitamin B6 (200 mg daily for 1 month) resulted in a 50% decrease in serum levels of phenobarbital and phenytoin.
- Concomitant use of vitamin B6 may enhance amiodarone-induced photosensitivity reactions. Doses of vitamin B6 greater than 5 to 10 mg/day should be avoided by those taking amiodarone.

Tell the doctor about other medicines the patient is taking including supplements and herbal products.

WHAT SHOULD YOU DO IF YOU MISS A DOSE?
If the patient misses a dose, just give the next dose and the subsequent doses at the usual recommended schedule.

Do not double the dose.

HOW SHOULD YOU KEEP THIS MEDICINE?
Store at temperatures not exceeding 30°C.

Since accidental overdosage of iron-containing preparations is a leading cause of fatal poisoning in children younger than 6 years old, patients should be advised to keep the product out of sight and reach of children.

SIGNS AND SYMPTOMS OF OVERDOSE
Iron
Large quantities of iron salts are toxic and fatal accidental ingestion in children is well recognized. Ingestion of 1 to 2 g of iron in children may be fatal.

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 hypotension, tachycardia (rapid heartbeat) and central nervous system (CNS) 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 – Occur several weeks after ingestion and is characterized by GI obstruction (blockage) and liver damage.

Vitamin B_6
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 TAKEN MORE THAN THE RECOMMENDED DOSAGE?
If the child has taken more than the recommended dosage, consult a doctor or contact a Poison Control Center right away.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE
- Iron therapy for longer than six months should be avoided except under the supervision of a doctor.
- Iron supplement should be used with extreme caution in those with chronic liver failure, alcoholic cirrhosis, chronic alcoholism, and pancreatic insufficiency.
- Use with caution in those with a history of gastritis, peptic ulcer, and GI bleeding.
- Individuals with an active or suspected infection; or those with elevated serum ferritin levels should generally avoid iron supplements.
- A moderate increase in iron stores has been associated with an increased risk of ischemic heart disease and cancer.
- Administration of doses of vitamin B12 greater than 10 mcg daily may produce a hematological response in those with anemia secondary to folate deficiency; indiscrimate use may mask the precise diagnosis.
- Do not take more than the recommended dose.
- Do not use after the expiry date on the label.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?
- Before starting the medicine particularly in preterm/low birth weight infants and in young children with iron deficiency anemia.
- If any undesirable effect occurs.

AVAILABILITY
Ferlin®Syrup (Oral Drops) in amber bottle of 15 mL.
Ferlin®Syrup in amber bottle of 120 mL.

DATE OF REVISION OF PATIENT INFORMATION LEAFLET (PIL):

Manufactured by Amherst Laboratories, Inc.
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