**NEONATAL FE- iron, folic acid, cyanocobalamin, ascorbic acid tablet, film coated**
**SLV PHARMACEUTICALS LLC DBA AUM PHARMACEUTICALS**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

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**NEONATAL FE**

**WARNING: If you are pregnant, nursing or taking medication, consult your doctor before use. Accidental overdose of iron containing products is a leading cause of fatal poisoning in children under 6. In case of accidental overdose, call a doctor or Poison Control Center immediately.**

## DESCRIPTION

Each green film-coated tablet for oral administration contains:

| | |
|---|---|
| Iron (Ferronyl) | 90 mg |
| Folic Acid | 1000 mcg |
| Vitamin $B_{12}$ (Cyanocobalamin) | 12 mcg |
| Vitamin C (Ascorbic acid) | 120 mg |

**Inactive Ingredients:** Microcrystalline cellulose, DI-Calcium phosphate, stearic acid, magnesium stearate, croscarmellose sodium, silicon dioxide, Titanium dioxide, HPMC E15, HPMC E5/E6, FD&C YELLOW # 5(LAKE), FD&C BLUE # 1 (LAKE ), FD&C YELLOW # 6 (LAKE).

## CLINICAL PHARMACOLOGY

Oral iron is absorbed most efficiently when administered between meals. Iron is critical for normal hemoglobin synthesis to maintain oxygen transport energy production and proper function of cells. Adequate amounts of iron are necessary for effective erythropoiesis. Iron also serves as a cofactor of several essential enzymes, including cytochromes, which are involved in electron transport. Folic acid is required for nucleoprotein synthesis and the maintenance of normal erythropoiesis. Folic acid is the precursor of tetrahydrofolic acid, which is involved as a cofactor for transformylation reactions in the biosynthesis of purines and thymidylates of nucleic acids. Deficiency of folic acid may account for the defective deoxyribonucleic acid (DNA) synthesis that leads to megaloblast formation and megaloblastic macrocytic anemias. Vitamin $B_{12}$ is essential to growth, cell reproduction, hematopoiesis, nucleic acid, and myelin synthesis. Deficiency may result in megaloblastic anemia or pernicious anemia.

## INDICATIONS

NEONATAL FE Rx Prenatal Vitamin With ferronyl iron Vitamin is indicated for the treatment of all anemias that are responsive to oral iron therapy. These include: hypochromic anemia associated with pregnancy, chronic and/or acute blood loss, metabolic disease, postsurgical convalescence, and dietary needs.

## CONTRAINDICATIONS

Hypersensitivity to any of the ingredients. Hemolytic anemia, hemochromatosis, and hemosiderosis are contraindications to iron therapy.

## WARNING

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

### Warning

Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. KEEP THIS PRODUCT OUT OF THE REACH OF CHILDREN. In case of accidental overdose, call a doctor or poison control center immediately.

## PRECAUTIONS

Dosing for elderly patients should be cautious. Due to the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy, dosing should start at the lower end of the dosing range.

### General

Take 2 hours after meals. Do not exceed recommended dose. Discontinue use if symptoms of intolerance appear. The type of anemia and underlying cause or causes should be determined before starting therapy with NEONATAL FE tablets. Ensure Hgb, Hct, reticulocyte count are determined before starting therapy and periodically thereafter during prolonged treatment.

Periodically review therapy to determine if it needs to be continued without change or if a dose change is indicated. This product contains FD&C Yellow No. 5 (tartrazine, which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

### Folic Acid

Folic acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive. Pernicious anemia should be excluded before using these products since folic acid may mask the symptoms of pernicious anemia.

### Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

### Geriatric Use

Dosing for elderly patients should be cautious. Due to the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy, dosing should start at the lower end of the dosing range.

## ADVERSE REACTIONS

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

## DRUG INTERACTIONS

Prescriber should be aware of a number of iron/drug interactions, including antacids, tetracyclines, or fluoroquinolones.

## OVERDOSAGE

Symptoms: abdominal pain, metabolic acidosis, anuria, CNS damage, coma, convulsions, death, dehydration, diffuse vascular congestion, hepatic cirrhosis, hypotension, hypothermia, lethargy,

nausea, vomiting, diarrhea, tarry stools, melena, hematemesis, tachycardia, hyperglycemia, drowsiness, pallor, cyanosis, lassitude, seizures, and shock.

## DOSAGE AND ADMINISTRATION

One tablet daily or as directed by a physician.

## NOTICE

Contact with moisture can discolor or erode the tablet.

Do not chew tablet.

## HOW SUPPLIED

**NEONATAL FE** (NDC 73317-8222-3) is a green, round shaped, film-coated tablet and packaged in bottles of 90. Store at 25°C (77°F). Excursions permitted to 15°-30°C (59°-86°F). (See USP Controlled Room Temperature).

**To report** a serious adverse event or obtain product information, call 866-760-6565

Dispensed by Prescription

This product is a prescription-folate with or without other dietary ingredients that – due to increased folate levels increased risk associated with masking of $B_{12}$ deficiency (pernicious anemia) requires administration under the care of a licensed medical practitioner (61 FR 8760).1-3 The most appropriate way to ensure pedigree reporting consistent with these regulatory guidelines and safety monitoring is to dispense this product only by prescription (Rx). This is not an Orange Book product. This product may be administered only under a physician's supervision and all prescriptions using this product shall be pursuant to state statutes as applicable. The ingredients, indication or claims of this product are not to be construed to be drug claims.

1. Federal Register Notice of August 2, 1973 (38 FR 20750)

2. Federal Register Notice of October 17, 1980 (45 FR 69043, 69044)

3. Federal Register Notice of March 5, 1996 (61 FR 8760)

AUM Pharmaceuticals does not represent these product codes to be National Drug Codes (NDC) .Product codes are formatted according to standard industry practice, to meet the formatting requirement by pedigree reporting and supply chain control including pharmacies.

## THERAPEUTIC GUIDELINES FOR THE PATIENT

Some facts you should know about Iron Deficiency Anemia

Iron Deficiency Anemia, or IDA, is a common type of anemia. It's a condition in which blood lacks an adequate supply of healthy red blood cells. These cells carry oxygen to tissues. It is oxygenated blood that gives your body energy and your skin a healthy color.

As the name suggests, Iron Deficiency Anemia results from insufficient iron. Your body needs iron to make a substance called hemoglobin. It's the hemoglobin in red blood cells that enables them to carry oxygen.

What causes IDA?

There are many causes of IDA. These include:

- A diet consistently low in iron
- Blood loss due to heavy menstrual bleeding
- Poor iron absorption from food due to intestinal surgery or diseases of the intestine
- Pregnancy (when the need for iron increases significantly)

Women in general are at higher risk of IDA, not only because they lose blood during menstruation but also because their bodies store less iron.

How common is it?

IDA is a common nutritional deficiency, with women most widely affected. Up to 20% of women have IDA.

What are the symptoms?

Some of the symptoms most commonly associated with IDA are fatigue, weakness, and headache. Symptoms may also include light-headedness, pale skin, shortness of breath, and cold hands and feet, among others. As the body becomes more deficient in iron and anemia worsens, the symptoms worsen as well.

How is IDA diagnosed?

A diagnosis is made primarily through blood tests. The doctor checks your hematocrit, the percentage of your blood volume made up of red blood cells and hemoglobin. A lower than normal hemoglobin level indicates anemia. Also, blood tests for IDA typically include a measurement of ferritin, a protein that helps store iron in your body. When the level of ferritin is low, usually the level of iron is, too. If a patient tests positive for IDA, additional tests may be ordered to identify an underlying cause.

Does IDA lead to health complications?

Mild cases of IDA usually don't cause complications. However, left untreated, IDA can increase in severity and contribute to serious health problems. For example, it may lead to a rapid or irregular heartbeat, a complicated pregnancy that can put the mother at risk for a premature delivery or low-birth-weight baby, and delayed growth in infants and children. The good news is that, because IDA is easily treatable, its potential health consequences are generally avoidable.

How is IDA treated?

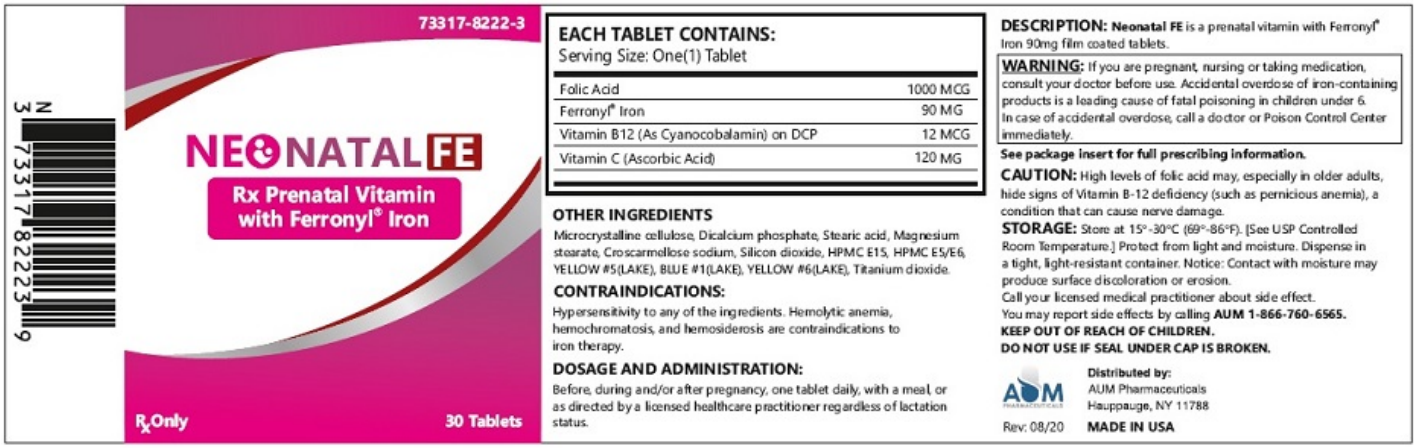
It's essential to increase the amount of iron in your diet. Foods rich in iron include meat, fish, poultry, and whole grain breads. However, in most cases of IDA, diet alone isn't enough to correct the problem. Iron supplementation is usually needed for several months. Your doctor has prescribed NEONATAL FE, a safe and effective iron supplement to help restore your body's iron to normal levels. Plus, it offers the convenience of once-daily dosing. Together with an iron-rich diet, taking NEONATAL FE every day can make a big difference in helping restore your body's iron, and with it your energy and overall feeling of well-being.

*If you have questions about **NEONATAL FE** please call:* **866-760-6565**

AUM Pharmaceuticals

320 Oser Ave,

Hauppauge, NY 11788-3608




# NEONATAL FE

iron, folic acid, cyanocobalamin, ascorbic acid tablet, film coated

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:73317-8222 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **FOLIC ACID** (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8) | FOLIC ACID | 1000 ug |
| **IRON PENTACARBONYL** (UNII: 6WQ62TAQ6Z) (FERROUS CATION - UNII:GW89581OWR) | FERROUS CATION | 90 mg |
| **CYANOCOBALAMIN** (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204) | CYANOCOBALAMIN | 12 ug |
| **ASCORBIC ACID** (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R) | ASCORBIC ACID | 120 mg |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |
| **CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS** (UNII: L11K75P92J) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **HYPROMELLOSES** (UNII: 3NXW29V3WO) | |
| **FD&C YELLOW NO. 5** (UNII: I753WB2F1M) | |
| **FD&C YELLOW NO. 6** (UNII: H77VEI93A8) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | green | **Score** | no score |
| **Shape** | ROUND | **Size** | 11mm |
| **Flavor** | | **Imprint Code** | |

| Contains | |
|---|---|

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| 1 | NDC:73317-8222-3 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 09/24/2020 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| unapproved drug other | | 09/24/2020 | |

## Labeler - SLV PHARMACEUTICALS LLC DBA AUM PHARMACEUTICALS (081225162)

## Registrant - SLV PHARMACEUTICALS LLC DBA AUM PHARMACEUTICALS (081225162)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| SLV PHARMACEUTICALS LLC DBA AUM PHARMACEUTICALS | | 081225162 | manufacture(73317-8222) |

Revised: 9/2020 SLV PHARMACEUTICALS LLC DBA AUM PHARMACEUTICALS