

IFEREX 150 FORTE- iron, cyanocobalamin and folic acid capsule
Nnodum Pharmaceuticals

IFEREX™ 150 Forte

Polysaccharide Iron Complex

Hematinic Capsules

NDC 63044-0198-01

WARNINGS:

Folic acid alone is improper therapy for the treatment of pernicious anemia and other megaloblastic anemias where vitamin B-12 is deficient.

PRECAUTIONS:

Folic acid in doses above 0.1 mg - 0.4 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive.

Pediatric Use Safety and effectiveness in pediatric patients has not been established.

SAFE HANDLING WARNING:

Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6.

Keep this products out of the reach of children. In case of accidental overdose, call a doctor or poison control immediately.

DOSAGE AND ADMINISTRATION:

Adults: iFerex 150 Forte is to be taken one capsule once a day or as prescribed by a physician.

iFerex 150 Forte PACKAGE LABEL/PRINCIPAL DISPLAY PANEL

iFerex 150 Forte 10 x 10 Unit Dose Capsules

Nnodum Corp
Printed Side
T123003D

NDC 63044-0198-62

**iFerex
150 Forte**

ZIK&S

**Polysaccharide Iron
Complex Hematinic**

**10x10 Unit
Dose Capsules**

Glue

DESCRIPTION:

iFerex 150 Forte Capsules are a highly water soluble complex of iron, low molecular weight polysaccharide and vitamins.

CLINICAL PHARMACOLOGY:

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

A radiolabeled tracer study in man demonstrated that absorption of polysaccharide iron is comparable to that of ferrous sulfate. Clinical studies demonstrate that polysaccharide iron produces good hematopoietic response as shown by increases in hemoglobin and hematocrit in children and adult patients. Polysaccharide iron is effective in maintaining the hematopoietic status in end-stage kidney disease patients receiving epoetin Alfa therapy.

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 is required for the maintenance of normal erythropoiesis, nucleoprotein and myelin synthesis, and reproduction and normal growth. Intrinsic factor, a glycoprotein secreted by the gastric mucosa, is required for active absorption of Vitamin B-12 from the gastrointestinal tract.

INDICATIONS OF USEAGE:

For treatment of iron deficiency anemia and/or nutritional megaloblastic anemias due to inadequate diet.

CONTRAINDICATIONS:

iFerex 150 Forte is contraindicated in patients with a known hypersensitivity to any of the components of this product. Hemochromatosis and hemochromatosis are contraindications to iron therapy.

Supplement Facts

Per 10x10 Unit Dose Capsule	Amount per Serving	% DV*
Iron	150 mg	270%
Folic Acid	1 mg	20%
Vitamin B12	25 mcg	410%
Iron	150 mg	270%

*% Daily Value based on a 2000 Calorie Diet

INACTIVE INGREDIENTS:

Microcrystalline Cellulose, Croscarmellose, Dicalcium Phosphate, Stearic Acid, Pharmaceutical Glaze, Magnesium Stearate, Iron Oxides, Titanium Dioxide, FD&C Red #40 Lake and FD&C Blue #1 Lake.

Manufactured for Nnodum Pharmaceuticals, Corp., Cincinnati, OH 45240



**iFerex
150 Forte**

**10x10
Unit
Dose
Capsules**

Rx Only

NDC 63044-0198-62

**iFerex
150 Forte**

**Polysaccharide Iron
Complex Hematinic**

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 poison control center immediately.

WARNINGS:

Folic acid alone is ineffective therapy in the treatment of pernicious anemia and other megaloblastic anemias unless vitamin B-12 is added.

PRECAUTIONS:

General: The type of anemia and the underlying cause or causes should be determined before starting therapy with iFerex 150 Forte. Since the anemia may be a result of a systemic or localized defect in iron metabolism, the underlying cause or causes should be corrected, if possible.

Folic acid in doses above 5 mg daily may obscure pernicious anemia in the hematologic remission can occur while neurological manifestations remain progressive.

ADVERSE REACTIONS:

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

OVERDOSE:

The clinical course of acute iron overdose can be variable. Initial symptoms may include abdominal pain, nausea, vomiting, diarrhea, dark stools, melena, hematemesis, hypotension, tachycardia, metabolic acidosis, hypoglycemia, delirium, coma, seizures, pulmonary edema, hypoxia, hypoxemia, shock and coma.

The LD₅₀ of the polysaccharide iron complex was determined to be greater than 5000 mg, ranging in rats. Chronic toxicity studies in rats and dogs administered polysaccharide-iron complex showed that a daily dosage of 500 mg, ranging for three months had no adverse effects.

DOSEAGE AND ADMINISTRATION:

Adults: iFerex 150 Forte is to be taken one capsule once a day or as prescribed by a physician.

STORAGE:

Store at 20°C-25°C (68°-77°F); excursions to 15°C-30°C (59°-86°F).

HOW SUPPLIED:

iFerex 150 Forte capsules are available in unit dose blister packs, 10 capsules per card.

2005

Prints/Black PMS 3278

iFerex 150 Forte 100 Capsules

DESCRIPTION: iFerex 150 Forte capsules are maroon with the marking "Z198". It is a product of ferrous iron complexed to a low molecular weight polysaccharide.

INDICATIONS AND USAGE: iFerex 150 Forte is indicated for the prevention and treatment of iron deficiency anemia and/or nutritional megaloblastic anemia.

CONTRAINDICATIONS: iFerex 150 Forte is contraindicated in patients with a known hypersensitivity to any of the components of this product. Hemochromatosis and hemosiderosis are contraindications to iron therapy.

DOSE AND ADMINISTRATION: Adults: 1 capsule daily or as directed by your physician.

ADVERSE EVENTS: You should call your doctor for medical advice about adverse events. To report a serious adverse event, contact Niodum Pharmaceuticals, 1761 Tennessee Ave., Suite D, Cincinnati, OH, 45229.

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 poison control immediately.

Supplement Facts
 Serving Size 1 capsule Servings Per Container 100

	Amount Per Serving	% Daily Value*
Folic Acid	1,000 mcg	250%
Vitamin B12	25 mcg	416%
Iron	150 mg	833%

*Percent Daily Values are based on a diet of other people's misdeeds.

Other ingredients: Microcrystalline Cellulose, Gelatin, Magnesium Stearate, D&C Red #28, Titanium Dioxide, FD&C Red #3, D&C Yellow #10, and FD&C Blue #1.

KEEP THIS PRODUCT AND ALL DRUGS OUT OF REACH OF CHILDREN. DISPENSE IN A TIGHT, LIGHT-RESISTANT CONTAINER WITH A RESISTANT CLOSURE.

STORAGE: Store at 20°C-25°C (68°-77°F); excursions permitted to 15°C-30°C (59°-86°F).

Distributed by Niodum Pharmaceuticals, Cincinnati, OH 45229
 NP 6/18/09 Rev. 05/11 LC-11014

ZIKS NDC 63044-0198-01

iFerex 150 Forte
 Dietary Supplement

100 Capsules **Rx Only**



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IFEREX 150 FORTE

iron, cyanocobalamin and folic acid capsule

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:63044-198
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IRON (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)	IRON	150 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	25 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
GELATIN (UNII: 2G86QN327L)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:63044-198-01	100 in 1 BOTTLE		
2	NHRIC:63044-198-62	10 in 1 BOX		
2		10 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
dietary supplement		12/01/2021	

Supplement Facts

Serving Size :

Serving per Container :

	Amount Per Serving	% Daily Value
color		
imprint		
shape		
scoring	1	
size (solid drugs)	7 mm	

Labeler - Nnodum Pharmaceuticals (960457273)

Establishment

Name	Address	ID/FEI	Business Operations
Contract Pharmacal Corporation		057795122	manufacture

Revised: 12/2023

Nnodum Pharmaceuticals