HEMATOGEN FA - ferrous fumarate, ascorbic acid, folic acid, cyanocobalamin capsule
Nnodum 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.

Hematogen FA

DESCRIPTION

CONTENTS : Each maroon and brown soft gelatin capsule contains:

Ferrous fumarate .....200 mg

(66 mg elemental iron)

Ascorbic acid .....250 mg

Folic acid .....1 mg

Cyanocobalamin .....10 mcg

DISCUSSION : The amount of elemental iron and the absorption of the iron components of commercial iron preparations vary widely. It is further established that certain "accessory components" may be included to enhance absorption and utilization of iron. Hematogen FA Capsules are formulated to provide the essential factors for a complete, versatile hematinic.

ACTIONS

HIGH ELEMENTAL IRON CONTENT: Ferrous fumarate, used in Hematogen FA Capsules, is an organic iron 1,2 complex which has the highest elemental iron content of any hematinic salt - 33% This compares with 20% for ferrous sulfate (heptahydrate) and 13% for ferrous gluconate.

MORE COMPLETE ABSORPTION: It has been repeatedly shown that Ascorbic acid, when given in sufficient amounts, can increase the absorption of ferrous Iron from the gastrointestinal tract. The absorption promoting effect is mainly due to the reducing action of ascorbic acid within the gastrointestinal lumen, which helps to prevent or delay the formation of insoluble or less dissociated ferric compounds. Iron absorption has been shown to increase sharply with increasing amounts of ascorbic acid, showing a gain in absorption of approximately 40% at 250 mg. Above 250 mg, the gain becomes insignificant, with an additional gain of only approximately 8% at 500 mg. Each Hematogen FA capsule contains 250 mg of ascorbic acid, believed to be the optimal amount

PROMOTES MOVEMENT OF PLASMA IRON: Ascorbic acid also plays an important role in the movement of plasma iron to storage depots in the tissues .The action, which leads to the transport of plasma iron to ferritin, presumably involves its reducing effect, converting transferrin iron from the ferric to the ferrous state. There is also evidence

that ascorbic acid improves iron utilization, presumably as a further result of its reducing action and some evidence that effect upon erythropoiesis. Ascorbic acid is further alleged to enhance the conversion of folic acid to a more physiologically active form, folinic acid, which would make it even more important in the treatment of anemia since it would aid in the utilization of dietary folic acid."

EXCELLENT ORAL TOLERATION: Ferrous fumarate is used in Hematogen FA Capsules because it is less likely to cause the gastric disturbances so often associated with oral iron therapy. Ferrous fumarate has a low ionization constant and high solubility in the entire pH range of the gastrointestinal tract. It does not precipitate proteins or have the astringency of more ionizable forms of iron, and does not interfere with proteolytic or diastatic activities of the digestive system. Because of excellent oral toleration, Hematogen FA Capsules can usually be administered between meals when iron absorption is maximal.

FOLIC ACID SUPPLEMENTATION: The use of supplemental folic acid may be indicated in patients with increased requirements for this vitamin, such as iron deficiency anemia. Folic acid administration may 12 reduce the risk of neural tube defects in the developing fetus . Folic acid has also been shown to reduce circulating homocysteine levels in the blood . Folate as 5-methyltetrahydrofolate and B as methylcobalamin are involved in the remethylation reaction of homocysteine to methionine. Elevated homocysteine plasma levels are associated with increased risk of preeclampsia, neural tube defects, myocardial infarction and artherosclerosis.

TOXICITY: Ferrous fumarate was found to be the least toxic of three popular oral iron salts, with an oral LD of 630 mg/kg. In the same report, the LD of ferrous gluconate was reported to be 320 mg/kg and ferrous sulfate 230 mg/kg.

INDICATIONS

For the treatment of all anemias responsive to oral iron therapy, such as hypochromic anemia associated with pregnancy, chronic or acute blood loss, dietary restriction, metabolic disease and post-surgical convalescence.

CONTRAINDICATIONS

Hemochromatosis and hemosiderosis are contraindications to iron therapy. Folic acid is contraindicated in patients with pernicious anemia (see PRECAUTIONS).

WARNING

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6 years of age. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

PRECAUTIONS

Folic acid should not be prescribed until the diagnosis of pernicious anemia has been

eliminated, since it can 14 alleviate the hematologic manifestations, while allowing neurological damage to continue undetected.

ADVERSE REACTIONS

Average capsule doses in sensitive individuals or excessive dosage may cause nausea, skin rash, vomiting, diarrhea, precordial pain, or flushing of the face and extremities.

DOSAGE AND ADMINISTRATION

Usual adult dose is 1 soft gelatin capsule daily.

HOW SUPPLIED

Capsules NDC 63044-632-17, Unit Dose Box 100

CAUTION: Federal law prohibits dispensing without prescription.

Manufactured by:

Catalent Australia PTY LTD

Distributed by:

Nnodum Pharmaceuticals

Cincinnati, Ohio 45240

BIBILOGRAPHY

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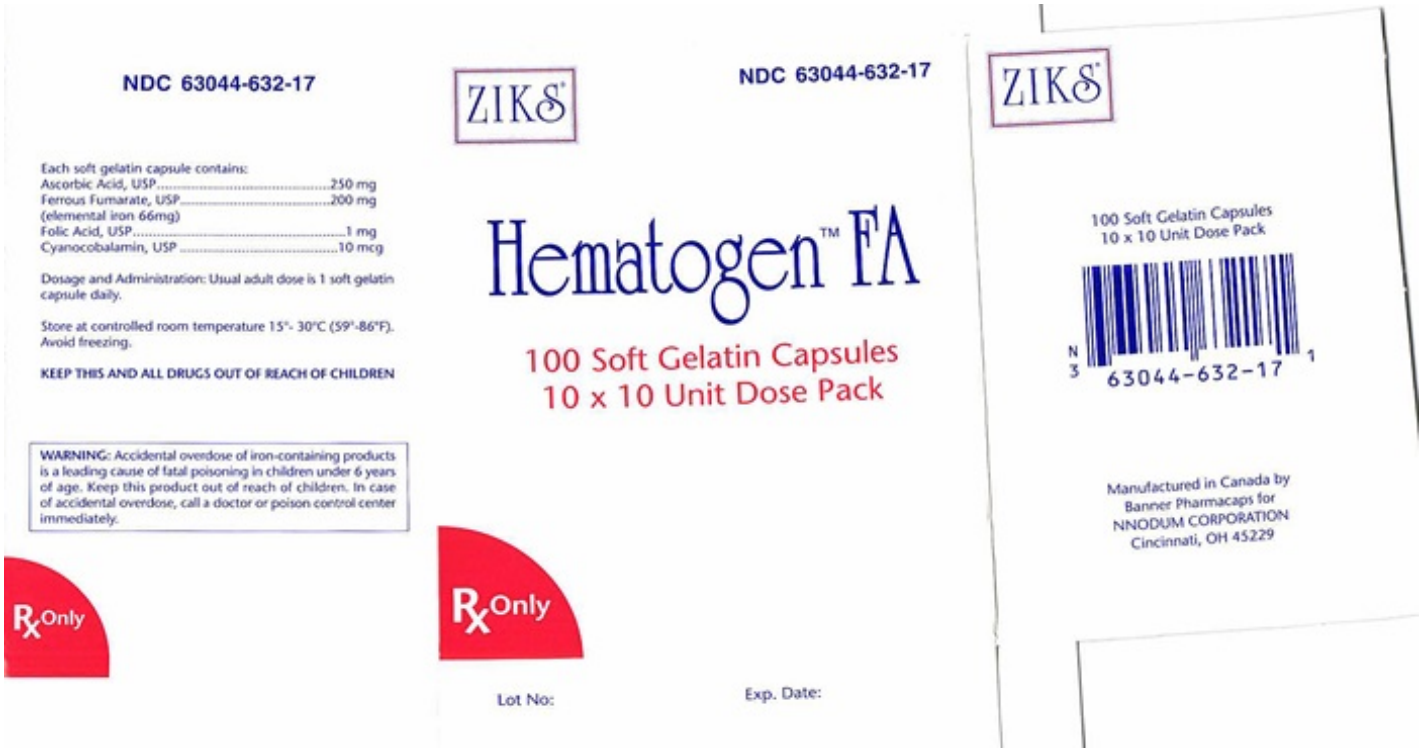
early- onset cerebral and peripheral occlusive disease - effects 01 pyridoxine and folic acid treatment." Atheroscle- rosi~ 1990; 812004-6. "Ka'1!J S. Wong PWK, NoruslS-t.x:"Homocysteinemla due_to folate deficiency." Me- tabolism~9$1!"4S8-62. ,~ BH.SI8w..-SO';Savage DG, Lindernbaum J. "Dia9nosis of cobalamin deficiency. "IL usefulness of serum methylmalonic acid and total homocysteine concentrations. Am J. Hema- 1011990; 34 90-98. "'Dekker GA, de Vries JI, Doelitzsch PM, Huijgens PC, von Blomberg BM, Jakobs, C, van Geijn HP 1985 "Underj:ging disorder associated with severe early-onset preeclampsia." Am. J. Obstet. Gy- necol. 173: 1042-1046. Mills JL, McPartlin JM, Kirke PN, Lee Y J, Conley MR, Weir DG, Scott JM 1995. "Ho-mocysteine metabolism in pregnancies complicated by neural-tube defects." Lancet. 345: 149-151. " Steegers-Theunissen RP, Boers GH, Blom HJ, Nijhuis JG, Thomas CM, Borm GF, Eskes TK. 1995. "Neural tube defects and elevated homocysteine levels in amniotic fluid." Am. J. Obstel Gynecol172 1436-1441. "Landgren F. Is- raelsson B, Lindgren A, Hultberg B, Andersson A, Brattstrom L 1995. "Plasma homocysteine in acute my- ocardial infarction: Homocysteine-lowering effect of folic acid." J. Intern. Med. 237: 381-388. '3Mayer EL, Ja-cobsen DW, Robinson K. 1996. "Homocysteine and Coronary Atherosclerosis." J.Am. Coli. Cardiol27: 517-27.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



HEMATOGEN FA

ferrous fumarate, ascorbic acid, folic acid, cyanocobalamin capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63044-632
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	66 mg
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	250 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	10 ug

Product Characteristics

Color	brown (maroon;brown)	**Score**	no score
Shape	CAPSULE	**Size**	1mm
Flavor		**Imprint Code**	none
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63044-632-17	10 in 1 BOX	01/01/2005	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/2005	

Labeler - Nnodum Pharmaceuticals (960457273)

Registrant - Nnodum Pharmaceuticals (960457273)

Establishment

Name	Address	ID/FEI	Business Operations
Contract Pharmacal Corporation		057795122	manufacture(63044-632)

Revised: 12/2023 Nnodum Pharmaceuticals