

HEMATOGEN[®] - ferrous fumarate, ascorbic acid, intrinsic factor and 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 Softgel capsule

Ferrous fumarate (66 mg elemental iron) USP..... 200 mg
 Ascorbic acid USP..... 250 mg
 Desiccated stomach powder..... 100 mg
 (Contains: Intrinsic factor),
 Cyanocobalamin USP.....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[®],[®] Capsules are formulated to provide the essential factors for a complete, versatile hematinic.

ACTIONS/CLINICAL PHARMACOLOGY

HIGH ELEMENTAL IRON CONTENT: Ferrous fumarate, used in Hematogen[®],[®] Capsules, is an organic iron 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.[®] Hematogen[®],[®] contains 66 mg of elemental iron.

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[®],[®] 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 it may have a direct 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[®],[®] 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[®],[®] Capsules can usually be administered between meals when iron absorption is maximal.

FACILITATES ABSORPTION OF VITAMIN B12 : It is now known that "Intrinsic Factor" is essential

for the adequate alimentary absorption of vitamin B. The inclusion of desiccated stomach powder 12 with oral vitamin B will furnish sufficient intrinsic factor to assure absorption of the vitamin 12

only

TOXICITY: Ferrous fumarate was found to be the least toxic of three popular oral iron salts, with an oral LD50 of 630 mg/kg. In the same report, the LD50 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.

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.

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 or extremities.

DOSAGE AND ADMINISTRATION:

Usual adult dose is 1 soft gelatin capsule daily.

HOW SUPPLIED:

Each Red soft gelatin capsule is imprinted with "Ziks631" on one side. **NDC 63044-0631-19** 10 x 10, unit dose packs, in packs of 100's.

Store at controlled between temperature 15Â°- 30Â°C (59Â°- 86Â°F). Protect from direct / excessive heat 40Â°C (104Â°F). Avoid freezing.

1 BIBLIOGRAPHY: Berk, M.S. and Novich, M.A.: 'Treatment of Iron Deficiency Anemia With Ferrous

2 Fumarate," Am. J. Obst. & Gynec., 203-206, 1962. Shapleigh, J.B., and Montgomery, A.; Am. Pract. &

3 Dig. Treat. 10-461, 1959. Brise, H. and Hallberg, L.: "Effect of Ascorbic Acid on Iron Absorption," Acta.

4 5 Med. Scand. 171 :376, 51 -58,1962. New Drugs, p. 309, AMA, Chicago, 1966. Mazur, A., Green, S. and Carleton, A.: "Mechanism of Plasma Iron Incorporation into Hepatic Ferritin," J. of Bio. Chem.

6 3:595-603, 1960. Greenberg, S.M., Tucker, A.E., Mathues, H. and J.D.: "Iron Absorption and

7 Metabolism, I. Interrelationship of Ascorbic Acid and Vitamin E," J. Nutrition 63:19-31, 1957. Moore, C. V., and Dubach, R.: "Observations on the Absorption of Iron From Foods Tagged with Radioiron,

8 "Trans. Assoc. Amer. Physic. 64:245, 1951. Steinkamp, R., Dubach, R. and Moore, C.Y. "Studies in

9 Iron Transportation and Metabolism," Arch. Int. Med. 95:181, 1955. Gorten, M.K. and Bradley, J.E.: "The Treatment of Nutritional Anemia in Infancy and Childhood with Oral Iron and Ascorbic

10 Acid,"J. Pediatrics, 45: 1, 1954. Mazur, A.: "Role of Ascorbic Acid in the Incorporation of Plasma

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Iron

11 into Ferritin." An. N.Y. Acad. Sci. 92:223-229, 1961. COX, E. V. et al.: "The Anemia of Scurvy," Amer. J.

12 Med. 42:220-227, 1967. Berk, L. et al.: "Observations on the Etiologic Relationship of Achylia

13 Gastrica to Pernicious Anemia, X," N. Eng. J. Med. 239:911-913, 1948. Hall, B.E.: "Studies on the

14 Nature of the Intrinsic Factor of Castle," Brit. Med. J. 2:585-589,1950. Wallerstein, R.O. et al.: "Observations on the Etiologic Relationship of Achylia Gastrica to Pernicious Anemia, XV" J. Lab

15 & Clin. Med. 41 :363-375, 1953. Castle, W.B.: "Observations on the Etiologic Relationship of Achylia

16 Gastrica to Pernicious Anemia, 1," Am. J. Med. Sc.178:748-764, 1929.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



HEMATOGEN			
ferrous fumarate, ascorbic acid, intrinsic factor , cyanocobalamin capsule			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:63044-631
Route of Administration	ORAL	DEA Schedule	
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
FERROUS FUMARATE (FERROUS CATION)	FERROUS CATION	66 mg	
ASCORBIC ACID (ASCORBIC ACID)	ASCORBIC ACID	250 mg	

8/19/2016		Hematogen Softgel capsule	
INTRINSIC FACTOR (INTRINSIC FACTOR)		INTRINSIC FACTOR	100 mg
CYANOCOBALAMIN (CYANOCOBALAMIN)		CYANOCOBALAMIN	10 ug
Product Characteristics			
Color	RED	Score	no score
Shape	OVAL	Size	4mm
Flavor		Imprint Code	ziks;631
Contains			
Packaging			
#	Item Code	Package Description	Multilevel Packaging
1	NDC:63044-631-19	100 BLISTER PACK (BLISTER PACK) in 1 BOX	contains a BLISTER PACK
1		1 CAPSULE (CAPSULE) in 1 BLISTER PACK	This package is contained within the BOX (63044-631-19)

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		05/10/2007	

Labeler - Nnodum Pharmaceuticals (960457273)

Registrant - Nnodum Pharmaceuticals (960457273)

Establishment			
Name	Address	ID/FEI	Operations
Catalent Australia PTY LTD		753617638	analysis, manufacture

Revised: 03/2014

Nnodum Pharmaceuticals