

**HEMATOGEN FORTE - ferrous fumarate, ascorbic acid, folic acid, cyanocobalamin capsule, gelatin coated  
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.*

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**Hematogen Forte**

**DESCRIPTION**

Each brown soft gelatin capsule contains:

|                         |        |
|-------------------------|--------|
| Ferrous fumarate.....   | 460 mg |
| (151 mg elemental iron) |        |
| Ascorbic acid.....      | 60 mg  |
| Folic acid.....         | 1 mg   |
| Cyanocobalamin.....     | 10 mcg |

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 Forte Capsules are formulated to provide the essential factors for a complete, versatile hematinic.

**Inactive Ingredients:** Soybean oil, Lecithin, Glycerin, hydrogenated soybean oil, Yellow Beewax, Titanium Oxide.

**ACTIONS/CLINICAL PHARMACOLOGY**

**High Elemental Iron Content:** Ferrous fumarate, used in Hematogen Forte Capsules, is an organic iron complex which has the highest elemental iron content of any hematinic salt - 33%. This compares with 20% for 1,2 ferrous sulfate (heptahydrate) and 13% for ferrous gluconate. Hematogen Forte contains 151 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 help to prevent or delay the formation of insoluble or less dissociated ferric compounds.

**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 Forte 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 Forte 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 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 methyltetrahydrofolate and B<sub>12</sub> 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 atherosclerosis.

**Toxicity:** Ferrous fumarate was found to be the least toxic of three popular oral iron salts, with an oral LD<sub>50</sub> 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 AND USAGE**

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). Soybean oil, Lecithin, Di Calcium phosphate anhydrous, Beeswax yellow, hydrogenated soybean oil.

### **WARNING**

**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.

## **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.

## **PRECAUTIONS**

Folic acid should not be prescribed until the diagnosis of pernicious anemia has been eliminated, since it can alleviate the hematologic manifestations, while allowing neurological damage to continue undetected

### **Pediatric Use**

Safety and effectiveness in pediatric patients has not been established.

### **Geriatric Use**

Clinical studies on this product have not been performed in sufficient numbers of subjects aged 65 and over to determine whether elderly subjects respond differently from younger subjects. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosage range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of noncomitant

## **DOSAGE AND ADMINISTRATION**

Usual adult dose is 1-2 soft gelatin capsules daily, or as directed by a physician.

## **HOW SUPPLIED**

Each brown soft gelatin capsule is imprinted with "ziks633" on one side. NDC 63044-0633-21, 10 x 10, Unit Dose Packs, In Packs of 100's.

Store at controlled room temperature 15°- 30°C (59°- 86°F). Avoid excessive heat 40°C (104°F). Avoid freezing.

## **BIBLIOGRAPHY**

1Berk, M.S. and Novich, M.A.: "Treatment of Iron Deficiency Anemia With Ferrous Fumarate," Am. J. Obst. & 3 Gynec., 203-206, 1962. Shapleigh, J.B., and Montgomery, A.:Am. Pract. & Dig. Treat. 10-461, 1959. Brise, H. and Hallberg, L.: "Effect of Ascorbic Acid on Iron Absorption," Acta. Med. Scand.171:376, 51-58,19624 5 New Drugs, p. 309, AMA, Chicago, 1966. Mazur, A., Green, S. and Carleton, A,: "Mechanism of Plasma 6 Iron Incorporation into Hepatic Ferritin"J. Bio. Chem. 3:595-603, 1960. Greenberg, S.M. Tucker, A. E., Mathues, H and J.D.: "Iron Absorption and Metabolism, I. Interrelationship of Ascorbic Acid and Vitamin E," 7 J. Nutrition 63:19-31, 1957. Moore, C.V. and Dubach, R. "Observations on the Absorption of Iron from 8 Foods Tagged with Radioiron" Trans. Assoc. Amer. Physic. 64:245, 1951. Steinkamp, R. Dubach, R. and 9 Moore, C.V.: "Studies in 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 Acid,"J. Pediatrics, 45:1,1954. 10Mazur, A.: "Role of Ascorbic Acid in the Incorporation of Plasma 11 Iron into Ferritin," Ann. 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. McEvoy, G.K., Ed.: AHFS Drug Information, p. 2667-2669, Am. Soc. Hosp.13 Pharm., Bethesda, 1996. Franken DG, Boers GH, Blom HJ, Trijbels JM. "Effect of various regimens of vitamin B and folic acid on mild hyperhomocysteinemia in

vascular patients." J. Inherit. Metab. Dis. 1994; 6 14 17:159-62. Brattstrom L, Israelsson B, Norrving B, et al. "Impaired homocysteine metabolism in early-onset cerebral and peripheral occlusive disease - effects of pyridoxine and folic acid treatment." 15 Atherosclerosis 1990; 81: 2004-6. Kang S. Wong PWK, Norusis M. "Homocysteinemia due to folate 16 deficiency." Metabolism 1987; 36: 458-62. Alien RH, Stabler SP, Savage DG, Lindernbaum J. "Diagnosis of cobalamin deficiency." 17 Am. J. Hematol. 1990; 34: 90-98. Dekker GA, de Vries JI, Doelitzsch PM, Huijgens PC, von Blomberg BM, Jakobs, C, van Geijn HP. 1985. "Underlying disorder associated with severe early-onset preeclampsia." Am. J. 18 Obstet. Gynecol. 173:1042-1048. Mills JL, McPartlin JM, Kirke PN, Lee YJ, Conley MR, Weir DG, Scott JM. 1995. "Homocysteine metabolism in pregnancies complicated by neural-tube defects." Lancet. 345: 149- 19 151. 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. Obstet. Gynecol. 172:1436-1441. 20Landgren F, Israelsson B, Lindgren A, Hultberg B, Andersson A, Brattstrom L. 1995. "Plasma homocysteine in 21 acute myocardial infarction: Homocysteine-lowering effect of folic acid." J. Intern. Med. 237: 381-388. Mayor EL, Jacobsen DW, Robinson K. 1996. "Homocysteine and Coronary Atherosclerosis." J. Am. Coll. Cardiol. 22 23 27:517-27. Berenbaum, M.C. et al.: Blood, 15:540,1960. Drug Information for the Health Care Professional, p.1365-1368, U. S. Pharmacopeial Conven., Rockville, 1995.

**Manufactured by:**

**Catalent Australia PTY LTD**

**Distributed by:**

**Nnodum Pharmaceuticals**

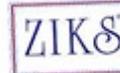
**Cincinnati, Ohio 45229**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 63044-633-21



NDC 63044-633-21



Each soft gelatin capsule contains:

|                        |        |
|------------------------|--------|
| Ferrous Fumarate, USP  | 460 mg |
| (151mg elemental iron) |        |
| Ascorbic Acid, USP     | 60 mg  |
| Folic Acid, USP        | 1 mg   |
| Cyanocobalamin, USP    | 10 mcg |

Dosage and Administration: 1-2 soft gelatin capsules daily, or as directed by a physician. See package insert for complete prescribing information.

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

KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN

**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.

Rx Only

1

# Hematogen<sup>TM</sup> Forte

Liquid - Iron in a soft gelcap

100 Soft Gelatin Capsules  
10 x 10 Unit Dose Pack

**ALLERGY ALERT:** Contains a soy product.

Rx Only

Lot No:

Exp. Date:

100 Soft Gelatin Capsules  
10 x 10 Unit Dose Pack

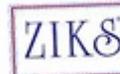


Manufactured in Canada by  
Banner Pharmacaps for  
NNODUM CORPORATION  
Cincinnati, OH 45229

NDC 63044-633-21



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10 x 10 Unit Dose Pack

**ALLERGY ALERT:** Contains a soy product.

Rx Only

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Exp. Date:

100 Soft Gelatin Capsules  
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Manufactured in Canada by  
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Cincinnati, OH 45229

## HEMATOGEN FORTE

ferrous fumarate, ascorbic acid, folic acid, cyanocobalamin capsule, gelatin coated

### Product Information

**Product Type**

HUMAN PRESCRIPTION DRUG

**Item Code (Source)**

NDC:63044-633

**Route of Administration**

ORAL

## Active Ingredient/Active Moiety

| Ingredient Name                                                               | Basis of Strength | Strength |
|-------------------------------------------------------------------------------|-------------------|----------|
| <b>FERROUS FUMARATE</b> (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR) | FERROUS CATION    | 151 mg   |
| <b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)     | ASCORBIC ACID     | 1 mg     |
| <b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)           | FOLIC ACID        | 10 mg    |
| <b>CYANOCOBALAMIN</b> (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)   | CYANOCOBALAMIN    | 10 mg    |

## Inactive Ingredients

| Ingredient Name                                    | Strength |
|----------------------------------------------------|----------|
| <b>SOYBEAN OIL</b> (UNII: 241ATL177A)              |          |
| <b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)        |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                 |          |
| <b>HYDROGENATED SOYBEAN OIL</b> (UNII: A2M91M918C) |          |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)         |          |

## Product Characteristics

|                 |         |                     |          |
|-----------------|---------|---------------------|----------|
| <b>Color</b>    | BROWN   | <b>Score</b>        | no score |
| <b>Shape</b>    | CAPSULE | <b>Size</b>         | 6mm      |
| <b>Flavor</b>   |         | <b>Imprint Code</b> | ziks;633 |
| <b>Contains</b> |         |                     |          |

## Packaging

| # | Item Code        | Package Description                                     | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------------------------------------------|----------------------|--------------------|
| 1 | NDC:63044-633-21 | 10 in 1 BOX                                             | 05/10/2007           |                    |
| 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<br>other |                                          | 05/10/2007           |                    |

**Labeler** - Nnodum Pharmaceuticals (960457273)

**Registrant** - Nnodum Pharmaceuticals (960457273)