

Drug Monograph

Drug Name: **Hematogen™ (ferrous fumarate/ascorbic acid/intrinsic factor/cyanocobalamin) softgel**
 Drug Class: **Antianemic Agent, Iron supplement, Oral**
 Prepared For: **MO HealthNet**
 Prepared By: **Conduent**

New Criteria

Revision of Existing Criteria

Executive Summary

Purpose: The purpose of this monograph is to provide a review of new therapy to determine whether the reviewed drug should be made available on an open access basis to prescribers, require a clinical edit or require prior authorization for use.

Dosage Forms: Hematogen is available as a softgel capsule containing ferrous fumarate 200 mg USP (elemental iron 66 mg), ascorbic acid 250 mg USP, desiccated stomach powder (intrinsic factor) 100 mg and cyanocobalamin 10 mcg USP.

Manufacturer: Distributed by: Nnodum Pharmaceuticals, Cincinnati, OH 45229.

Summary of Findings: The efficacy of Hematogen has not been established or evaluated in any clinical trials to date. However, the ingredients contained within Hematogen have been shown to help raise iron levels, increase iron and vitamin B absorption, and promote red blood cell health.

Status Recommendation: Clinical Edit PA Required
 Open Access PDL

Type of PA Criteria: Appropriate Indications Non-Preferred
 No PA Required Preferred

Purpose

The purpose of this monograph is to provide a review of new therapy to determine whether the reviewed drug should be considered a prior authorization drug, a clinical edit drug or an open access drug. While prescription expenditures are increasing at double-digit rates, payers are evaluating ways to control these costs by influencing prescriber behavior and guide appropriate medication usage. This review will assist in the achievement of qualitative and economic goals related to health care resource utilization. Restricting the use of certain medications can reduce costs by requiring documentation of appropriate indications for use, and where appropriate, encourage the use of less expensive agents within a drug class.

Introduction ⁽²⁾

Anemia is the most common blood condition in the United States, affecting nearly 6% of the population. Anemia is defined as having a low number of red blood cells, which is determined through laboratory testing. There are over 400 types of anemias which are categorized into 3 groups. Anemia due to blood loss, anemia caused by reduced or faulty red blood cell production, or anemia caused by the destruction of red blood cells. Red blood cells contain hemoglobin which is the main oxygen carrying protein in the blood. When hemoglobin is low, less oxygen is being carried to vital organs. In turn, less oxygen being transported throughout the body can lead to unwanted side effects. Symptoms of anemia may include fatigue, headache, dizziness, weakness, unusually fast heartbeat, shortness of breath, cold hands and feet, skin that is pale or yellow in nature.

Dosage Form ⁽¹⁾

Hematogen is available as a softgel capsule containing ferrous fumarate 200 mg USP (elemental iron 66 mg), ascorbic acid 250 mg USP, desiccated stomach powder (intrinsic factor) 100 mg and cyanocobalamin 10 mcg USP.

Manufacturer ⁽¹⁾

Distributed by: Nnodum Pharmaceuticals, Cincinnati OH 45229.

Indication(s) ⁽¹⁾

Hematogen is indicated 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.

Clinical Efficacy ^(1,3)

Ferrous fumarate is an organic iron complex which contains the highest amount of elemental iron content of any hematinic salt (33%). Erythropoiesis is dependent upon the available concentration of iron and erythropoietin in the plasma.

Ascorbic acid, when given in adequate doses, helps promote iron absorption by preventing or delaying the formation of insoluble or less dissociated ferric compounds. It is also believed that ascorbic acid plays a role in the movement of plasma iron to storage depots within the tissues as well as increases iron utilization in various metabolic pathways.

Intrinsic factor is a protein made in the stomach that is essential for vitamin B12 absorption in the large intestine.

Cyanocobalamin is a key nutrient that helps promote red blood cell and nerve health.

Contraindications ⁽¹⁾

Hemochromatosis and hemosiderosis are contraindications to iron therapy.

Warnings and Precautions ^(1,3)

- Iron supplementation is only useful for anemias where iron deficiency co-exist, before starting therapy the underlying cause(s) should be determined.
- Accidental overdose of iron-containing products can lead to fatal poisoning in children under 6 years of age. Keep out of reach of children.

Adverse Effects ⁽¹⁾

Hematogen may cause nausea, vomiting, diarrhea, constipation, precordial pain, flushing of the face or extremities and possible skin rash.

Drug Interactions ^(1,3)

Iron containing preparations may bind to other medications reducing its absorption and/or the other medication's bioavailability. Administration of certain foods and medications should be avoided within the hour before or 2 hours after taking iron supplements.

Dosage and Administration ⁽¹⁾

- One softgel capsule taken by mouth daily or as directed by a physician.
 - Administer with a full glass of water or juice.

Cost

Generic Name	Brand Name	Manufacturer	Dose	Cost**/ Month
Ferrous fumarate/ascorbic acid/intrinsic factor/cyanocobalamin	Hematogen™	Nnodum Pharmaceuticals	200 mg (elemental iron 66 mg), 250 mg, 10 mcg	\$7.80

** Wholesale Acquisition Cost

Conclusion

Hematogen efficacy has not been evaluated by the FDA at this time. The ingredients contained within Hematogen softgels have been shown to help treat and or improve anemias responsive to oral iron therapy. Hematogen is typically taken once a day between meals for maximal iron absorption.

Recommendation

MO HealthNet Division recommends Open Access status for this product.

References

- 1) Hematogen Softgel (Ferrous fumarate, ascorbic acid, intrinsic factor, cyanocobalamin) product information. Cincinnati, OH: Nnodum Pharmaceuticals; 2014 March 26.
URL: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=c36cb9d3-f0a3-4d34-92f2-8ab281b26b7d>. Accessed 08 August 2021.
- 2) MedlinePlus [Internet]. Bethesda (MD): National Library of Medicine (US); [updated 2021 July 28]. Anemia; [updated 2021 July 28; reviewed 2016 July 29; cited 2021 Aug 8]; Available from: <https://medlineplus.gov/anemia.html>
- 3) Clinical Pharmacology [Accessed 2021 August]. Available at URL: <https://www.clinicalkey.com/pharmacology/>.

Prepared by: James Lyon, PharmD
Date: August 9, 2021