

TRICON- tricon 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.

TRICON™ Capsules

Liver Stomach Concentrate Capsule

Hematinic Conentrate with Intrinsic Factor

NDC 63044-635-10

Rx Only

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.

A Highly Potent Oral Antianemia Preparation

DESCRIPTION

Each TRICON™ Capsule contains:

Special liver-stomach concentrate

(containing intrinsic factor) 240 mg

Vitamin B12 (activity equivalent)15 mcg

Iron, elemental (ferrous fumarate)110 mg

Vitamin C (ascorbic acid) 75 mg

Folic acid 0.5 mg

with other factors of vitamin B complex present in the liver-stomach concentrate.

Inactive ingredients: Citric acid, D&C Yellow No. 10, ethylcellulose, FD&C Blue No. 1, FD&C Red #28, gelatin, lecithin, magnesium stearate, pharmaceutical glaze, silicon dioxide, simethicone, sodium benzoate, sodium citrate, sorbic acid, starch, and titanium dioxide.

CLINICAL PHARMACOLOGY: Vitamin B12 with Intrinsic

Factor: when secretion of intrinsic factor in gastric juice is inadequate or absent (e.g., Addisonian pernicious anemia or after gastrectomy), vitamin B12 in physiologic doses is absorbed poorly, if at all. The resulting deficiency of vitamin B12 leads to the clinical

manifestations of pernicious anemia. Similar megaloblastic anemias may develop in fish tapeworm (*Diphyllobothrium latum*) infection or after a surgically created small bowel blind loop; in these situations, treatment requires freeing the host of the parasites or bacteria that appear to compete for the available vitamin B12. Strict vegetarianism and malabsorption syndromes may also lead to vitamin B12 deficiency. In the latter case, parenteral therapy or oral therapy with so-called massive doses of vitamin B12 may be necessary for adequate treatment of the patient.

Potency of intrinsic factor concentrates is determined physiologically, i.e., by their use in patients with pernicious anemia. The liver-stomach concentrate with intrinsic factor and the vitamin B12 contained in two TRICON™ Capsules provide 1½ times the minimum amount of therapeutic agent that, when given daily in an uncomplicated case of pernicious anemia, will produce a satisfactory response and relief of anemia and symptoms.

Concentrates of intrinsic factor derived from hog gastric, pyloric, and duodenal mucosa have been used successfully in patients who lack intrinsic factor.

Folic Acid: Folic acid deficiency is the immediate cause of most, if not all, cases of nutritional megaloblastic anemia and of the megaloblastic anemias of pregnancy and infancy; usually, it is also at least partially responsible for the megaloblastic anemias of malabsorption syndromes, e.g., tropical and nontropical sprue.

It is apparent that in vitamin B12 deficiency (e.g., pernicious anemia) lack of this vitamin results in impaired utilization of folic acid. There are other evidences of the close folic acid-vitamin B12 interrelationship: (1) B12 influences the storage, absorption, and utilization of folic acid, and (2) as a deficiency of B12 progresses, the requirement for folic acid increases. However, folic acid does not change the requirements for vitamin B12.

Iron: A very common anemia is that due to iron deficiency. In most cases, the response to iron salts is prompt, safe, and predictable. Within limits, the response is quicker and more certain to large doses of iron than to small doses.

Each TRICON™ (hematinic concentrate with intrinsic factor) Capsule furnishes 110 mg of elemental iron (as ferrous fumarate) to provide a maximum response.

Ascorbic Acid: Vitamin C plays a role in anemia therapy. It augments the conversion of folic acid to its active form, folinic acid. In addition, ascorbic acid promotes the reduction of ferric iron in food to the more readily absorbed ferrous form. Severe and prolonged vitamin C deficiency is associated with an anemia that is usually hypochromic but occasionally megaloblastic in type.

INDICATIONS AND USAGE

TRICON™ is a multifactor preparation effective in the treatment of anemias that respond to oral hematinics, including pernicious anemia and other megaloblastic anemias and also iron deficiency anemia. Therapeutic quantities of hematopoietic factors that are known to be important are present in the recommended daily dose.

CONTRAINDICATIONS

Hemochromatosis and hemosiderosis are contraindications to iron therapy.

PRECAUTIONS

General

Anemia is a manifestation that requires appropriate investigation to determine its cause or causes.

Folic acid alone is unwarranted in the treatment of pure vitamin B12 deficiency states, such as pernicious anemia. Folic acid may obscure pernicious anemia in that the blood picture may revert to normal while neurological manifestations remain progressive.

As with all preparations containing intrinsic factor, resistance may develop in some cases of pernicious anemia to the potentiation of absorption of physiologic doses of vitamin B12. If resistance occurs, parenteral therapy or oral therapy with so-called massive doses of vitamin B12 may be necessary for adequate treatment of the patient. No single regimen fits all cases, and the status of the patient observed in follow-up is the final criterion for adequacy of therapy. Periodic clinical and laboratory studies are considered essential and are recommended.

Pregnancy

Teratogenic Effects

Pregnancy Category C:

Animal reproduction studies have not been conducted with TRICON™ Capsules. It is also not known whether TRICON™ Capsules can cause fetal harm when administered to pregnant women or can affect reproduction capacity. TRICON™ Capsules should be given to pregnant women only if clearly needed.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when TRICON™ is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in pediatric patients below the age of 10 have not been established.

Geriatric Use

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 dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function and of concomitant disease or other drug therapy.

ADVERSE REACTIONS

Rarely, iron in therapeutic doses produces gastrointestinal reactions, such as diarrhea or constipation. Reducing the dose and administering it with meals will minimize these effects in the iron-sensitive patient.

In extremely rare instances, skin rash suggesting allergy has been noted following the oral administration of liver-stomach material. Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

OVERDOSAGE

Symptoms: Those of iron intoxication, which may include pallor and cyanosis, vomiting, hematemesis, diarrhea, melena, shock, drowsiness, and coma.

Treatment: For specific therapy, exchange transfusion and chelating agents. For general management, gastric and rectal lavage with sodium bicarbonate solution or milk, administration of intravenous fluids and electrolytes, and use of oxygen.

DOSAGE AND ADMINISTRATION

One capsule twice a day. (Two capsules daily produce a standard response in the average uncomplicated case of pernicious anemia.)

HOW SUPPLIED

TRICON™ Capsules are opaque brown NDC 63044-0635-10 Unit Dose Packs containing 10 capsules per card. 100 capsules.

Storage: Store at controlled room temperature 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F). [See USP Controlled Room Temperature.

Manufactured For
Nnodum Pharmaceuticals by Contract Pharmacal Corporation
135 Adams Avenue
Hauppauge, New York 11788

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Rx Only NDC 63044-635-01

Tricon

Capsules

100 Capsules

Manufactured for Nnodum Pharmaceuticals Corp.

483 Northland Blvd., Cincinnati, OH 45240



Only NDC 63044-635-01

Tricon Capsules

ematinic Concentrate
with Intrinsic Factor

Dietary Supplement

 **Nnodum
Pharmaceuticals**

100 Capsules

DO NOT USE IF IMPRINTED SAFETY SEAL
UNDER CAP IS BROKEN OR MISSING.

Supplement Facts

Serving Size: 1 Capsule

Serving Per Container: 100

Each Capsule Contains:	Amount per capsule	% Daily Value
Vitamin B-12 (Cyanocobalamin)	15 mcg	250%
Iron (Ferrous Fumerate)	110 mg	611%
Vitamin C (Ascorbic Acid)	75 mg	125%
Folic Acid	500 mcg	125%
Liver-Stomach Conc.	240 mg	DV not established

*Percent Daily Values based on a 2,000 calorie diet.

Other Ingredients: Gelatin, Pharmaceutical Glaze, Dicalcium Phosphate, Magnesium Stearate, FD&C Red No. 40 Lake, Titanium Dioxide, FD&C Red No. 3 Lake, FD&C Green No. 3 Lake and FD&C Blue No. 1 Lake.

Indications: For the dietary management of individuals with anemia. All substitutions using this product shall be pursuant to state statutes as applicable. This is not an Orange Book product.

How Supplied: Tricon® Capsules are scarlet/garnet, Supplied unit dose of 100 capsules. Storage: Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F). See USP Controlled Room Temperature. Protect from

... ..
light and moisture. Dispense in a tight, light-resistant container with a child-resistant closure as defined in the USP/NF.

USUAL ADULT DOSAGE: One capsule twice a day. (Two capsules daily produce a standard response in the average uncomplicated case of pernicious anemia).

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of the reach of children. In case of accidental overdose, call a doctor or poison control center immediately. If pregnant, or planning to become pregnant or are currently breast-feeding please contact your physician, or health-care provider before using or continued use.

Tricon CAPSULES Hematinic Concentrate with Intrinsic Factor dietary supplement 100 Capsules

To report a serious adverse event contact: 513-861-2329.

Manufactured For: Nnodum Pharmaceuticals Corp.

483 Northland Blvd., Cincinnati, Ohio 45240



res

TRICON

tricon capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:63044-635
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	15 ug
FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	110 mg
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	75 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	0.5 mg

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBIC ACID (UNII: X045WJ989B)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BROWN (opaque brown)	Score	no score
Shape	CAPSULE	Size	16mm
Flavor		Imprint Code	N635
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63044-635-10	10 in 1 BOX	05/20/2005	
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		05/20/2005	

Labeler - Nnodum Pharmaceuticals (960457273)

Establishment

Name	Address	ID/FEI	Business Operations
Contract pharmacal Corporation		057795122	MANUFACTURE(63044-635)

Revised: 12/2023

Nnodum Pharmaceuticals