DEXATRAN- multivitamin capsule
PureTek Corporation

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.

Dexatran Multivitamin

DESCRIPTION:

Each capsule contains:
Vitamin C (as sodium ascorbate).....200 mg
Thiamin (as thiamine mononitrate)..... 10 mg
Riboflavin..... 6 mg
Niacin (as niacinamide)..... 30 mg
Vitamin B6 (as pyridoxine hydrochloride)..... 5 mg
Folate (as folic acid)..... 1667 mcg DFE (1000 mcg folic acid)
Vitamin B12 (as cyanocobalamin)..... 15 mcg
Pantothenic Acid (as d-calcium pantothenate)..... 10 mg
Iron (as ferrous fumarate)..... 18 mg
Magnesium (as magnesium sulfate)..... 6.9 mg
Zinc (as zinc sulfate)..... 18.2 mg
Copper (as cupric sulfate)..... 0.8 mg
Manganese (as manganese sulfate)..... 1.3 mg

Other Ingredients:
Magnesium Stearate (vegetable source), Microcrystalline Cellulose, Silicon Dioxide, Vegetable Capsule.

Indications and Usage:

Dexatran™ is indicated to provide vitamin supplement to men and women. Folic acid is effective in the treatment of megaloblastic anemias due to a deficiency of folic acid (as may be seen in tropical or nontropical sprue) and in anemias of nutritional origin, pregnancy, infancy, or childhood.

Contraindications:

This product is contraindicated in patients with known hypersensitivity to any of its ingredients; also, all iron compounds are contraindicated in patients with hemosiderosis, hemochromatosis, or hemolytic anemias. Pernicious anemia is a contraindication, as folic acid may obscure its signs and symptoms.

Warnings:

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.

Accidental of folic acid alone is improper therapy for pernicious anemia and other megaloblastic anemias in which vitamin B_{12} is deficient.

Precautions:

Folic acid in doses above 0.1 mg daily may obscure pernicious anemia, in that hematologic remission can occur while neurological manifestations remain progressive.

There is a potential danger in administering folic acid to patients with undiagnosed anemia, since folic acid may obscure the diagnosis of pernicious anemia by alleviating the hematologic manifestations of the disease while allowing the neurologic complications to progress. This may result in severe nervous system damage before the correct diagnosis is made. Adequate doses of vitamin B_{12} may prevent, halt, or improve the neurologic changes caused by pernicious anemia.

The patient's medical conditions and consumption of other drugs, herbs, and/or supplements should be considered.

For use on the order of a healthcare practitioner.

Call your doctor about side effects. To report side effects, call **PureTek Corporation** at **1-877-921-7873** or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Drug Interactions:

Dexatran™ is not recommended for and should not be given to patients receiving levodopa because the action of levodopa is antagonized by pyridoxine. There is a possibility of increased bleeding due to pyridoxine interaction with anticoagulants (e.g., Aspirin, Heparin or Clopidogrel).

Adverse Reactions:

Folic Acid: Allergic sensitizations has been reported following both oral and parenteral administration of folic acid.

Ferrous Fumarate: Gastrointestinal disturbances (anorexia, nausea, diarrhea, constipation) occur occasionally, but are usually mild and may subside with continuation of therapy. Although the absorption of iron is best when taken between meals, giving **Dexatran™** after meals may control occasional gastrointestinal disturbances. **Dexatran™** is best absorbed when taken at bedtime.

Adverse reactions have been reported with specific vitamins and minerals but generally at levels substantially higher than those contained herein. However, allergic and idiosyncratic reactions are possible at lower levels. Iron, even at the usual recommended levels, has been associated with gastrointestinal intolerance in some patients.

OVERDOSE:

Iron: Signs and Symptoms: Iron is toxic. Acute overdosage of iron may cause nausea and vomiting and, in severe cases, cardiovascular collapse and death. Other symptoms include pallor and cyanosis, melena, shock, drowsiness and coma. The estimated overdose of orally ingested iron is 300 mg/kg body weight. When overdoses are ingested by children, severe reactions, including fatalities, have resulted. **Dexatran™** should be stored beyond the reach of children to prevent against accidental iron poisoning. **Keep this and all other drugs out of reach of children.**

Treatment:

For specific therapy, exchange transfusion and chelating agents shouldbe used. For general management, perform gastric lavage with sodium bicarbonate solution or milk.

Administer intravenous fluids and electrolytes and use oxygen.

Dosage and Administration:

Adults (persons over 12 years of age) one (1) **Dexatran™** capsule daily, between meals or as directed by a physician. Do not administer to children under the age of 12.

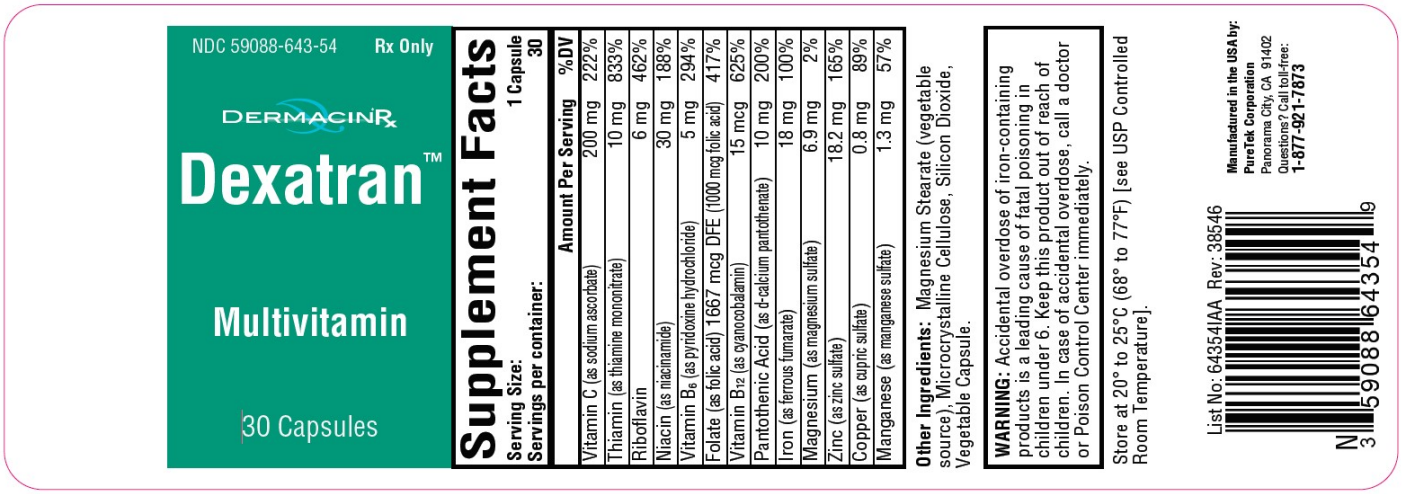
How Supplied:

Dexatran™ are transparent capsules in bottles containing 30 capsules – NDC 59088-643-54. Dispense in a tight, light-resistant container as defined in the USP/NF with a child resistant closure.

Do not use if bottle seal is broken. KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.
Store at controlled room temperature 20o to 25oC (68o to 77oF). [See USP].
Protect from light and moisture and avoid excessive heat.

Dexatran™

Manufactured in the USA by:
PureTek Corporation
Panorama City, CA 91402
Questions? Call toll-free:
1-877-921-7873



DEXATRAN

multivitamin capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:59088-643
Route of Administration	ORAL, CUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MAGNESIUM SULFATE HEPTAHYDRATE (UNII: SK47B8698T) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM SULFATE HEPTAHYDRATE	6.9 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	6 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	30 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	5 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	15 ug
CALCIUM PANTOTHENATE (UNII: 568ET80C3D) (PANTOTHENIC ACID - UNII:19F5HK2737)	PANTOTHENIC ACID	10 mg
SODIUM ASCORBATE (UNII: S033EH8359) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	200 mg
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	10 mg
ZINC SULFATE (UNII: 89DS0H96TB) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	18.2 mg
MANGANESE SULFATE (UNII: W00LYS4T26) (MANGANESE CATION (2+) - UNII:H6EP7W5457)	MANGANESE CATION (2+)	1.3 mg
FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	18 mg
CUPRIC SULFATE (UNII: LRX7AJ16DT) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	0.8 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
GELLAN GUM (LOW ACYL) (UNII: 7593U09I4D)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
WATER (UNII: 059QF0KO0R)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	brown (Light Brown With Specks)	**Score**	no score
Shape	CAPSULE	**Size**	23mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-643-54	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/15/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/15/2023	

Labeler - PureTek Corporation (785961046)

Revised: 2/2023 PureTek Corporation