

BENTIVITE- iron (as ferrous sulfate) and folic tablet
Lifsa Drugs LLC

Bentivite

HEALTH CLAIM:

Bentivite Tablets - Dietary Supplement

Dispensed by Prescription

Supplement Facts

Serving Size: 1 Tablet Serving per Bottle: 30		
Amount Per Serving:		% Daily Value
Iron (as ferrous sulfate)	35 mg	194%
Folic Acid	1 mg	417%

OTHER INGREDIENTS: Microcrystalline Cellulose, Dicalcium Phosphate Unmilled (Di-Tab), Stearic Acid, Croscarmellose Sodium, Magnesium Stearate and Silicon Dioxide.

DESCRIPTION:

Bentivite Tablets is an orally administered prescription vitamin formulation for the clinical dietary management of suboptimal nutritional status in patients where advanced folate supplementation is required and nutritional supplementation in physiologically stressful conditions for maintenance of good health is needed.

CONTRAINDICATIONS:

Bentivite Tablets are contraindicated in patients with a known hypersensitivity to any of the ingredients. Do not take this product if you are presently taking mineral oil, unless directed by a doctor.

WARNING:

This product is contraindicated in patients with a known hypersensitivity to any of the ingredients.

Bentivite tablets should only be used under the direction and supervision of a licensed medical practitioner. Use with caution in patients that may have a medical condition, are pregnant, lactating, trying to conceive, under the age of 18, or taking medications.

Pregnancy and Lactation

Bentivite is not intended for use in pregnant or lactating patients.

PRECAUTION:

Folic acid alone is improper therapy in the treatment of pernicious anemia and other

megaloblastic anemias where vitamin B is deficient. Folic acid in doses above 1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations progress. Bentivite Tablets should only be used under the direction and supervision of a licensed medical practitioner.

Do not take within 2 hours of taking oral tetracycline antibiotics, since oral iron products tend to interfere with absorption of tetracycline. May cause gastrointestinal discomfort, nausea, constipation or diarrhea. If you are pregnant or nursing a baby, seek advice of a health professional before using this product. U.S. Consumer Product Safety Commission requires that iron-containing medicine and vitamins with iron be packaged in child-resistant closures. Parents should always use properly re-secure safety closures.

ADVERSE REACTIONS:

Allergic sensitization has been reported following both oral and parenteral administration of folic acid. You may report side effects by calling the FDA at 1-800-FDA-1088.

DOSAGE & ADMINISTRATION:

Usual adult dose is 1 tablet taken orally once or twice daily or as prescribed by a licensed medical practitioner.

HOW SUPPLIED HEALTH CLAIM:

Bentivite Tablets are available as white, round tablets and are available in 30-count bottles (72336-014-01*). This product is not an Orange Book product.

Dispensed by Prescription[†]

Manufactured for: Lifsa Drugs LLC, New Brunswick, NJ 08901

Rev. 08/21

*Lifsa Drugs LLC does not represent these product codes to be National Drug Codes (NDC). Product codes are formatted according to standard industry practice, to meet the formatting requirement by pedigree reporting and supply-chain control including pharmacies.

[†]This product is a prescription-folate with or without other dietary ingredients that - due to increased folate levels increased risk associated with masking of B12 deficiency (pernicious anemia) requires administration under the care of a licensed medical practitioner (61 FR 8760).1-3 The most appropriate way to ensure pedigree reporting consistent with these regulatory guidelines and safety monitoring is to dispense this product only by prescription. This is not an Orange Book product. This product may be administered only under a physician's supervision and all prescriptions using this product shall be pursuant to state statutes as applicable. The ingredients, indication or claims of this product are not to be construed to be drug claims. 1. Federal Register Notice of August 2, 1973 (38 FR 20750) 2. Federal Register Notice of October 17, 1980 (45 FR 69043, 69044) 3. Federal Register Notice of March 5, 1996 (61 FR 8760)

STORAGE AND HANDLING:

Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F) [See USP

Controlled Room Temperature.] Protect from heat, light and moisture. Tamper Evident: Do not use if seal is broken or missing.

Distributed by: Lifsa Drugs LLC, NJ 08901

PACKAGE LABEL:

Supplement Facts

Bentivite Tablet	
Amount Per Serving	% Daily Value
Iron (as Ferrous Sulfate)	35mg 100%
Folic Acid	1mg 41%

INACTIVE INGREDIENTS:
Microcrystalline Cellulose, Dicalcium Phosphate Unmilled (Di-Tab), Stearic Acid, Croscarmellose Sodium, Magnesium Stearate, and Silicon Dioxide.

BENTIVITE

iron (as ferrous sulfate) and folic tablet

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:72336-014
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FERROUS SULFATE (UNII: 39R4TAN1VT) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	35 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
STEARIC ACID (UNII: 4ELV7Z 65AP)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z 6XB4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:72336-014-01	30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
dietary supplement		10/05/2021	

Supplement Facts

Serving Size :

Serving per Container :

	Amount Per Serving	% Daily Value
color		
shape		
size (solid drugs)	8 mm	
scoring	1	

Labeler - Lifsa Drugs LLC (081205160)

Revised: 10/2021

Lifsa Drugs LLC