

ZALVIT- ascorbic acid, cholecalciferol, thiamin, pyridoxal-5-phosphate, folic acid, methylcobalamin, calcium carbonate, ferrous gluconate, iodine tablet
NATIONAL BIO GREEN SCIENCES LIMITED LIABILITY COMPANY

Zalvit

HEALTH CLAIM:

Zalvit Tablets - Prenatal/Postnatal Dietary Supplement

Dispensed by Prescription

Supplement Facts		
Serving Size: 1 Tablet		
Serving per Bottle: 30		
Amount Per Serving:		% Daily Value
Vitamin C (as ascorbic acid)	125 mg	104%
Vitamin D3 (as cholecalciferol)	12.5 mcg (500 IU)	83%
Thiamin (Vitamin B1 as thiamin HCl)	1.4 mg	100%
Vitamin B6 (as pyridoxal 5' phosphate)	2.5 mg	125%
Folate	1,666 DFE (1 mg folic acid)	278%
Vitamin B12 (as methylcobalamin)	1,000 mcg	35,714%
Calcium (from calcium carbonate)	200 mg	15%
Iron (as ferrous gluconate)	13 mg	48%
Iodine (as potassium iodide)	150 mcg	52%

OTHER INGREDIENTS: Microcrystalline Cellulose, Silicon Dioxide and Magnesium Stearate.

DESCRIPTION:

Zalvit Tablets is a prescription dietary supplement for use throughout pregnancy, during the postnatal period for both lactating and non-lactating mothers, and throughout the childbearing years. Zalvit Tablets may be useful in improving the nutritional status of women prior to conception.

WARNING AND PRECAUTIONS

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. In case of accidental overdose, call a doctor or poison control center immediately.

CONTRAINDICATIONS:

Zalvit 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.

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. Zalvit Tablets should only be used under the direction and supervision of a licensed medical practitioner.

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:

Zalvit Tablets are available as white, round tablets and are available in 30-count bottles (72678-018-01*). This product is not an Orange Book product.

Dispensed by Prescription†

Manufactured for: National Bio Green Sciences Limited Liability Company, Branchburg, NJ 08876

Rev. 08/19

* National Bio Green Sciences Limited Liability Company 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: National Bio Green Sciences Limited Liability Company, Branchburg, NJ 08876

Packaging

Lot No.
Exp. Date

3 72678 01801

72678-018-01

Zalvit Tablets



30 Tablets

PRENATAL/POSTNATAL
Prescription Folic Acid-Containing
Dietary Supplement

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OTHER INGREDIENTS: Microcrystalline Cellulose
Silicon Dioxide, Magnesium Stearate.

size (solid drugs)	20 mm
scoring	1

Labeler - NATIONAL BIO GREEN SCIENCES LIMITED LIABILITY COMPANY (967054623)

Revised: 9/2019

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