

PRENATE MAX- beta-crotene, ascorbic acid, cholecalciferol, dl-alpha tocopherol acetate, pyridoxine hci, biotin, folic acid and l-5 mthf ca salt, cyanocobalamin, calcium carbonate, megnesium oxide, ferrous fumarate, postassium iodide, thiamin hci tablet
Allegis Pharmaceuticals, LLC

Prenate Max Tablets
PRENATAL/POSTNATAL
Dietary Supplement

Prenate Max - Dispensed by Prescription

Serving Size: 1 Tablet		
Servings Per Container: 30		
Each Tablet Contains:		%DV
Vitamin A (as beta-carotene)	300 mcg RAE	66%
Vitamin C (as ascorbic acid)	125 mg	140%
Vitamin D3 (as cholecalciferol)	12.5 mcg	30%
Vitamin E (as dl-alpha-tocopheryl acetate)	4.5 mg	33%
Vitamin B6 (as pyridoxine HCl)	20 mg	1117%
Folate (From 588 mcg folic acid and 442 mcg L-5 MTHF ca salt)	1750 mcg DFE	437.5%
Vitamin B12 (as cyanocobalamine)	0.03 mg	650%
Biotin	30 mg	10%
Calcium (from calcium carbonate)	100 mg	7.5%
Iron (as ferrous fumarate)	15 mg	83%
Iodine (as potassium iodide)	150 mcg	100%
Magnesium (as magnesium oxide)	20 mg	5%
Thiamin (as thiamin HCl)		1.4
mg 100%		

** Daily Values (DV) not established.

OTHER INGREDIENTS: Microcrystalline cellulose, powdered cellulose, silica, vegetable steric acid, croscarmellose sodium, vegetable magnesium stearate, coating (hypromellose, hydroxypropyl cellulose, titanium dioxide, polyehylene glycol).

Description

Prenate Max 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.

Prenate Max Tablets may be useful in improving the nutritional status of women prior to conception.

CONTRADINDICATIONS

Prenate Max Tablets are contraindicated in patients with a known hypersensitivity to any of the contained ingredients. Do not take this product if you are presently taking mineral oil, unless directed by a licensed medical practitioner.

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 the case of accidental overdose, call a doctor or poison control center immediately.

ADVERSE REACTIONS

Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

You may report side effects by calling Allegis Pharmaceuticals, Inc at 1-866-633-9033 or the FDA by calling 1-800-FDA-1088.

DOSAGE AND ADMINISTRATION

Before, during and/or after pregnancy, one tablet daily with food or as directed by a physician.

PRECAUTION:

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where Vitamin B12 is deficient. Folic acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations progress. Prenate Max Tablets should only be used under the direction and supervision of a licensed medical practitioner.

For use under the supervision of a licensed medical practitioner. Dispense in a tight, light resistant container as defined in the USP/NF in a child-resistant closure.

How Supplied

How Supplied

Prenate Max Tablets are available as white tablets with "225" embossed and are available in 30 count bottles (28595-727-30*).

Manufactured in the USA for:

Allegis Pharmaceuticals, Inc.

Canton, MS 39046

Rev 04/2025

Statements

These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease.

This product is not an Orange Book Product.

Dispense by Prescription**

*Allegis Pharmaceuticals, Inc. 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 requirements 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 a 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

Store at 20°-25°C (68°-77°F) excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature.] Protect from light and moisture.

Tamper evident: Do not use if seal is broken or missing.

Label

28595-717-30

**PRENATE
MAX Tablets**

Prenatal/Postnatal

**Dietary
Supplement**Dispensed by
Prescription**30 Tablets****Supplement Facts**

Serving Size: 1 Tablet Servings per container: 30

Amount Per Serving:	% Daily Value
Vitamin A (as Beta-carotene)	300 mcg RAE 66%
Vitamin C (as Ascorbic Acid)	125 mg 140%
Vitamin D3 (as Cholecalciferol)	12.5 mcg 30%
Vitamin E (as dl-Alpha Tocopherol Acetate)	4.5 mg 33%
Vitamin B6 (as Pyridoxine HCl)	20 mg 1117%
Biotin	30 mcg 10%
Folate (from 588 mcg folic acid and 442 mcg L-5 MTHF ca Salt)	1750 mcg DFE 437.5%
Vitamin B12 (as cyanocobalamin)	0.03 mg 650%
Calcium (as Calcium carbonate)	100 mg 7.5%
Magnesium (as Magnesium Oxide)	20 mg 5%
Iron (as Ferrous Fumarate)	15 mg 83%
Iodine (as Potassium Iodide)	150 mcg 100%
Thiamin (as Thiamin HCl)	1.4 mg 100%
**Daily Values (DV) not established.	

Manufactured in the USA for:
Allegis Pharmaceuticals, Inc.
 Canton, MS 39046
 Rev. 04/2025

**PRENATE MAX**

beta-croten, ascorbic acid, cholecalciferol, dl-alpha tocopherol acetate, pyridoxine hci, biotin, folic acid and l-5 mthf ca salt, cyanocobalamin, calcium carbonate, megnesium oxide, ferrous fumarate, postassium iodide, thiamin hci tablet

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:28595-717
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	125 mg
BETA CAROTENE (UNII: 01YAE03M7J) (BETA CAROTENE - UNII:01YAE03M7J)	BETA CAROTENE	0.3 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	0.0125 mg
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	4.5 mg
PYRIDOXINE HCL (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	20 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1.75 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	0.03 mg
BIOTIN (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	BIOTIN	0.03 mg
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	100 mg
FERROUS BISGLYCINATE (UNII: SFW1D987QV) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	15 mg
POTASSIUM IODIDE (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	IODIDE ION	0.15 mg
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CATION	20 mg
THIAMINE (UNII: X66NSO3N35) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.4 mg

Inactive Ingredients	
Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CELLULOSE ACETATE (UNII: 3J2P07GVB6)	
SILICA (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:28595-717-30	30 in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
dietary supplement		04/15/2025	

Supplement Facts	
Serving Size :	Serving per Container :
Amount Per Serving	% Daily Value
color	
shape	
imprint	
size (solid drugs)	19 mm
scoring	1

Labeler - Allegis Pharmaceuticals, LLC (792272861)
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Establishment			
Name	Address	ID/FEI	Business Operations
Formulation Tech Incorporated		062525910	manufacture