

PRENATAL PLUS- vitamin a acetate, .beta.-carotene, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, calcium carbonate, ferrous fumarate, zinc oxide, cupric oxide tablet, film coated

Amneal Pharmaceuticals LLC

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.

**Prenatal Plus
Vitamin and Mineral Tablet
Multi-Vitamin
Rx Only**

DESCRIPTION

Each Tablet Contains:

VITAMINS: Amount per Tablet

Vitamin A (from Acetate and Beta Carotene)	4000 IU
Vitamin C (Ascorbic Acid)	120 mg
Vitamin D-3 (Cholecalciferol)	400 IU
Vitamin E (dl- Alpha Tocopheryl Acetate)	22 mg
Thiamine (Vitamin B-1) (from Thiamine Mononitrate)	1.84 mg
Riboflavin (Vitamin B-2)	3 mg
Niacin (as Niacinamide)	20 mg
Vitamin B-6 (Pyridoxine HCl)	10 mg
Folic Acid	1 mg
Vitamin B-12 (Cyanocobalamin)	12 mcg

MINERALS: Amount per Tablet

Calcium (as Calcium Carbonate)	200 mg
Iron (from Ferrous Fumarate)	27 mg
Zinc (from Zinc Oxide)	25 mg
Copper (from Cupric Oxide)	2 mg

Other ingredients: croscarmellose sodium, FD&C Blue #2, FD&C Red #40, FD&C Yellow # 5, FD&C Yellow # 6, macrogol, magnesium stearate, microcrystalline cellulose, polyvinyl alcohol, silicon, starch, stearic acid, talc, titanium dioxide

INDICATIONS AND USAGE

To provide Vitamin and Mineral supplementation throughout pregnancy and during the postnatal period for both the lactating and non-lactating mother. It is also useful for improving nutritional status prior to conception.

WARNINGS

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under age 6. Keep this product out of the reach of children. In case of accidental overdose, call a doctor or Poison Control Center immediately.

PRECAUTIONS

Folic acid may partially correct the hematological damage due to Vitamin B12 deficiency of pernicious anemia, while the associated neurological damage progresses.

DOSAGE AND ADMINISTRATION

As a dietary adjunct before, during and after pregnancy, take one tablet daily with a meal, or as directed by a physician.

HOW SUPPLIED

Bottles of 100: NDC 65162-668-10

Bottles of 500: NDC 65162-668-50

Storage

**STORE AT CONTROLLED ROOM TEMPERATURE 15° to 30°C (59° to 86°F),
AVOID EXCESS HEAT.**

**Dispense in a well closed light-resistant container, with a child resistant cap.
KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN.
DO NOT USE IF INNER SAFETY SEAL IS BROKEN OR MISSING.**

Manufactured by:

Nexgen Pharma

Colorado Springs, CO 80905

Distributed by:

Amneal Pharmaceuticals

Glasgow, KY 42141

Rev. 09-2012

PRINCIPAL DISPLAY PANEL



PRENATAL PLUS

vitamin a acetate, .beta.-carotene, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, calcium carbonate, ferrous fumarate, zinc oxide, cupric oxide tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65162-668
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VITAMIN A ACETATE (UNII: 3LE3D9D6OY) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	3080 [iU]
BETA CAROTENE (UNII: 01YAE03M7J) (BETA CAROTENE - UNII:01YAE03M7J)	BETA CAROTENE	920 [iU]
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	120 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	400 [iU]
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	22 mg
THIAMINE MONONITRATE (UNII: 8K0I04919X) (Thiamine ION - UNII:4ABT0J945J)	THIAMINE	1.84 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	3 mg
NIACINAMIDE (UNII: 25X5118RD4) (NIACINAMIDE - UNII:25X5118RD4)	NIACINAMIDE	20 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	10 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	12 ug
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	200 mg
FERROUS FUMARATE (UNII: R5L488RYOQ) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	27 mg
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	25 mg
CUPRIC OXIDE (UNII: V1XJQ704R4) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	2 mg

Inactive Ingredients

Ingredient Name	Strength
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM ASCORBATE (UNII: S033EH8359)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBIC ACID (UNII: X045WJ989B)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCROSE (UNII: C151H8M554)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	yellow	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	G12
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65162-668-10	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/02/2009	
2	NDC:65162-668-50	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/02/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/02/2009	

Labeler - Amneal Pharmaceuticals LLC (123797875)

Establishment

Name	Address	ID/FEI	Business Operations
New Generation Wellness		806784679	analysis(65162-668) , manufacture(65162-668)

Revised: 3/2022

Amneal Pharmaceuticals LLC