

PRENATVITE PLUS- prenatalvite plus tablet
SLV PHARMACEUTICALS LLC DBA AUM PHARMACEUTICALS

PRENATVITE PLUS TABLETS Rx
Prenatal Vitamin Tablet with Prescription Folic Acid

DESCRIPTION

SUPPLEMENT FACTS:

Serving Size: One Tablet

PRENATVITE PLUS is an orally administered prenatal/postnatal prescription folic acid-containing dietary Supplement and should be administered under the supervision of a licensed medical practitioner.

Each PRENATVITE PLUS tablet contains:

VITAMIN A (AS ACETATE, BETA CAROTENE)	1200 MCG
VITAMIN C (ASCORBIC ACID)	120 MG
VITAMIN D3 (AS CHOLECALCIFEROL)	10 MCG
VITAMIN E (AS DL-ALPHA TOCOPHEROL ACETATE)	9.2 MG
VITAMIN B1 (AS THIAMINE MONONITRATE)	1.84 MG
VITAMIN B2 (AS RIBOFLAVIN)	3 MG
VITAMIN B3 (AS NIACINAMIDE)	20 MG
VITAMIN B6 (AS PYRIDOXINE HCL)	10 MG
FOLIC ACID	1000 MCG
VITAMIN B12 (AS CYANOCOBALAMIN)	12 MCG
CALCIUM (AS CALCIUM CARBONATE)	27 MG
IRON (AS FERROUS FUMARATE)	27 MG
ZINC (AS ZINC OXIDE)	25 MG
COPPER (AS CUPRIC OXIDE)	2 MG
INOSITOL	5 MG
CITRUS BIOFLAVONOIDS COMPLEX 50%	2 MG
BORON (AS BORON CITRATE)	0.2 MG

Other Ingredients:

microcrystalline cellulose, stearic acid, magnesium stearate, croscarmellose sodium, silicon dioxide, PEG-8000, talc, HPMC E15, HPMC E5/E6, FD&C RED #40 (LAKE), FD&C BLUE # 2 (LAKE FD&C YELLOW # 6 (LAKE).

INDICATIONS

PRENATVITE PLUS is a multi-vitamin/mineral prescription drug indicated for use in improving the nutritional status of women prior to conception, throughout pregnancy, and in the postnatal period for both lactating and nonlactating mothers.

CONTRAINDICATIONS

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

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.

CAUTION: High levels of folic acid may, especially in older adults, hide signs of Vitamin B-12 deficiency (such as pernicious anemia), a condition that can cause nerve damage.

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B 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 progress.

ADVERSE REACTIONS

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

DOSAGE AND ADMINISTRATION

One tablet daily or Take exactly as prescribed by your doctor.

Take **PRENATVITE PLUS** tablet each day at any time of day at about the same time each day.

PRENATVITE PLUS can be taken with or without food.

STORAGE

Store at 20-25°C (68-77°F) [See USP controlled room temperature].

Do not keep medicine that is out of date or that you no longer need.

Keep **PRENATVITE PLUS** Tablets and all medicines out of the reach of children.

NOTICE

Contact with moisture can discolor or erode the tablet.

HOW SUPPLIED

Bottles of 90 tablets each - NDC 73317-1150-9

To report a serious adverse event or obtain product information, call **631-524-5758**

Call your licensed medical practitioner about side effect.

You may report side effects by calling AUM 1-631-524-5758.

Manufactured and Distributed by:

AUM Pharmaceuticals
Hauppauge, NY 11788.

Made in USA

73317-1150-9

PrenatVite Plus
RX Prenatal Vitamin Tablet with Prescription Folic Acid

PRENATAL / POSTNATAL

R Only
Dietary Supplement
90 Tablets

AUM PHARMACEUTICALS

Each prenatal tablet contains the following ingredients for nutritional supplement:

Vitamin A (As Acetate and Beta Carotene)	1200 MCG
Vitamin C (Ascorbic Acid)	120 MG
Vitamin D3 (As Cholecalciferol)	10 MCG
Vitamin E (As Di-Alpha Tocopheryl Acetate)	9.2 MG
Vitamin B1 (As Thiamine Mononitrate)	1.84 MG
Vitamin B2 (Riboflavin)	3 MG
Vitamin B3 (As Niacinamide)	20 MG
Vitamin B6 (As Pyridoxine Hcl)	10 MG
Folic Acid	1000 MCG
Vitamin B12 (As Cyanocobalamin) On DCP	12 MCG
Calcium (Calcium Carbonate)	200 MG
Iron (As Ferrous Fumarate)	27 MG
Zinc (As Zinc Oxide)	25 MG
Copper (As Cupric Oxide)	2 MG
Inositol	5 MG
Citrus Bioflavonoid Complex 50%	2 MG
Boron (As Boron Citrate)	0.2 MG

OTHER INGREDIENTS
MICRO CRYSTALLINE CELLULOSE, STEARIC ACID, MAGNESIUM STEARATE, CROSCARMELOSE SODIUM, SILICON DIOXIDE, HPMC E15, HPMC E5/E6, PEG - 8000, TALC, FD&C RED # 40 (LAKE), FD&C BLUE # 2 (LAKE), FD&C YELLOW # 5 (LAKE).

Description: Prenatvite PLUS Tablet is an orally administered prenatal/postnatal prescription folic acid-containing dietary supplement and should be administered under the supervision of a licensed medical practitioner.

DOSAGE AND ADMINISTRATION: Before, during and/or after pregnancy, one tablet daily, with a meal, or as directed by a licensed healthcare practitioner regardless of lactation status. See package insert for full prescribing information.

WARNING: 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.

CAUTION: High levels of folic acid may, especially in older adults, hide signs of Vitamin B-12 deficiency (such as pernicious anemia), a condition that can cause nerve damage.

Store at 15-30° c (59-86° F). [See USP Controlled Room Temperature.] Protect from light and moisture. Dispense in a tight, light-resistant container. Notice: Contact with moisture may produce surface discoloration or erosion.

Call your licensed medical practitioner about side effect.
You may report side effects by calling **AUM 1-631-524-5758**.

Manufactured & Distributed By:
AUM Pharmaceuticals
Hauppauge, NY 11788.
Made in USA

AUM PHARMACEUTICALS

N 73317 11509 6

PRENATVITE PLUS

prenatvite plus tablet

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:73317-1150
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VITAMIN A (UNII: 81G40H8B0T) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	1200 ug
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	120 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	10 ug
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) (.ALPHA.-TOCOPHEROL - UNII:H4N855PNZ1)	.ALPHA.-TOCOPHEROL ACETATE	9.2 mg
THIAMINE (UNII: X66NSO3N35) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.84 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	3 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	20 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1B16Z)	PYRIDOXINE	10 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1000 ug
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	12 ug
FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	27 mg
INOSITOL (UNII: 4L6452S749) (INOSITOL - UNII:4L6452S749)	INOSITOL	5 mg
CITRUS BIOFLAVONOIDS (UNII: BD70459150) (HESPERIDIN - UNII:E750O06Y6O)	CITRUS BIOFLAVONOIDS	2 mg
CALCIUM (UNII: SY7Q814VUP) (CALCIUM - UNII:SY7Q814VUP)	CALCIUM	200 mg
BORON (UNII: N9E3X5056Q) (BORON - UNII:N9E3X5056Q)	BORON	0.2 mg
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	25 mg
CUPRIC OXIDE (UNII: V1XJQ704R4) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	2 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TALC (UNII: 7SEV7J4R1U)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 2--ALUMINUM LAKE (UNII: 4AQJ3LG584)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
---	-----------	---------------------	----------------------	--------------------

1	NHRIC:73317-1150-9	90 in 1 BOTTLE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
DIETARY SUPPLEMENT		02/03/2020		

Supplement Facts	
Serving Size :	Serving per Container :
Amount Per Serving	% Daily Value
color	
scoring	1
size (solid drugs)	5 mm
shape	

Labeler - SLV PHARMACEUTICALS LLC DBA AUM PHARMACEUTICALS (081225162)

Establishment			
Name	Address	ID/FEI	Business Operations
SLV PHARMACEUTICALS LLC DBA AUM PHARMACEUTICALS		081225162	repack(73317-1150)

Revised: 2/2020

SLV PHARMACEUTICALS LLC DBA AUM PHARMACEUTICALS