# PRENATVITE- prenatvite tablet SLV PHARMACEUTICALS LLC DBA AUM PHARMACEUTICALS

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# PRENATVITE TABLETS Rx

Prenatal Vitamin With Other Vitamins & Minerals For Nutritional Supplementation

# **DESCRIPTION**

#### **SUPPLEMENT FACTS:**

Serving Size: One Tablet

**PRENATVITE RX** is an orally administered prenatal dietary Supplement and should be administered under the supervision of a licensed medical practitioner.

Each PRENATVITE 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	)4.6 MG
VITAMIN B1 (AS THIAMINE MONONITRATE)	1.5 MG
VITAMIN B2 (AS RIBOFLAVIN)	1.7 MG
VITAMIN B3 (AS NIACINAMIDE)	18 MG
VITAMIN B6 (AS PYRIDOXINE HCL)	2.6 MG
FOLIC ACID	800 MCG
VITAMIN B12 (AS CYANOCOBALAMIN)	4 MCG
CALCIUM (AS CALCIUM CARBONATE & SULFATE)	263 MG
IRON (AS FERROUS FUMARATE)	27 MG
ZINC (AS ZINC OXIDE)	25 MG
INOSITOL	5 MG
CITRUS BIOFLAVONOIDS COMPLEX 50%	2 MG
BORON (AS BORON CITRATE)	0.2 MG

# Other Ingredients:

MICRO CRYSTALLINE CELLULOSE, DI CALCIUM PHOSPHATE, STEARIC ACID, CROSCARMELLOSE SODIUM, SILICON DIOXIDE, MAGNESIUM STEARATE, HPMC E15, HPMC E5/E6, PEG - 8000, TALC, FD&C RED # 40 (LAKE), FD&C YELLOW # 6 (LAKE), TRIACETIN.

#### INDICATIONS

**PRENATVITE RX** 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 RX** tablet each day at any time of day at about the same time each day. **PRENATVITE RX** 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 RX** 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 73317-1050-9

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

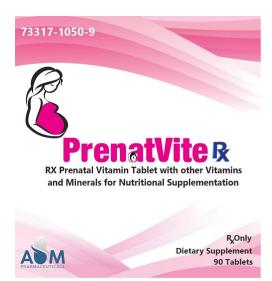
Call your licensed medical practitioner about side effect.

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

# Manufactured and Distributed by:

AUM Pharmaceuticals Hauppauge, NY 11788.

# Made in USA



Each prenatal tablet contains the following ingredients for nutritional supplement:

Vitamin A (As Acetate and Beta Carotene)		1200	MCG
Vitamin C (Ascorbic Acid)		100	MG
Vitamin D3 (As Cholecalciferol)		10	MCG
Vitamin E (As DI-Alpha Tocopheryl Acetate)		4.6	MG
Vitamin B1 (As Thiamine Mononitrate)		1.5	MG
Vitamin B2 (Riboflavin)		1.7	MG
Vitamin B3 (As Niacinamide)		18	MG
Vitamin B6 (As Pyridoxine Hcl)		2.6	MG
Folic Acid		800	MCG
Vitamin B12 (As Cyanocobalamin) On DCP		4	MCG
Calcium (As Calcium Carbonate and Sulfate)	)	263	MG
Iron (As Ferrous Fumarate)		27	MG
Zinc (As Zinc Oxide)		25	MG
Inositol		5	MG
Citrus Bioflavonoid Complex 50%		2	MG
Boron (As Boron Citrate)		0.2	MG

#### OTHER INGREDIENTS

MICRO CRYSTALLINE CELLULOSE, DI CALCIUM PHOSPHATE, STEARIC ACID, CROSCARMELLOSE SODIUM, SILICON DIOXIDE, MAGNESIUM STEARATE, HPMC E15, HPMC E5/E6, PEG - 8000, TALC, FD&C RED # 40 (LAKE), FD&C YELLOW # 6 (LAKE), TRIACETIN. **Description: Prenatvite RX Tablet** is an orally administered prenatal dietary supplement and should be administered under the supervision of a licensed medical practitioner.

See package insert for full prescribing information.

<u>WARNING</u>: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this out of reach of children. In case of accidental overdose, call a doctor or product 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.

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Store at 15-30 c (69-86 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





# **PRENATVITE**

prenatvite tablet

Product Information				
Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:73317-1050	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
VITAMIN A (UNII: 81G40 H8 B0 T) (VITAMIN A - UNII: 81G40 H8 B0 T)	VITAMIN A	1200 ug		
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	100 mg		
CHOLECALCIFEROL (UNII: 1C6 V77QF41) (CHOLECALCIFEROL - UNII:1C6 V77QF41)	CHOLECALCIFEROL	10 ug		
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0) (.ALPHATOCOPHEROL - UNII: H4N855PNZ1)	.ALPHATOCOPHEROL ACETATE	4.6 mg		
THIAMINE (UNII: X66NSO3N35) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.5 mg		
RIBO FLAVIN (UNII: TLM2976OFR) (RIBO FLAVIN - UNII: TLM2976OFR)	RIBOFLAVIN	1.7 mg		
NIACINAMIDE (UNII: 25X5118 RD4) (NIACINAMIDE - UNII:25X5118 RD4)	NIACINAMIDE	18 mg		
<b>PYRIDO XINE HYDRO CHLO RIDE</b> (UNII: 68 Y4CF58 BV) (PYRIDO XINE - UNII: KV2JZ1BI6Z)	PYRIDO XINE	2.6 mg		
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	800 ug		
CYANO COBALAMIN (UNII: P6 YC3EG204) (CYANOCOBALAMIN - UNII:P6 YC3EG204)	CYANOCOBALAMIN	4 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: BD70459I50) (HESPERIDIN - UNII:E750O06Y6O)	CITRUS BIOFLAVONOIDS	2 mg		
CALCIUM (UNII: SY7Q814VUP) (CALCIUM - UNII:SY7Q814VUP)	CALCIUM	263 mg		
<b>BORON</b> (UNII: N9E3X5056Q) (BORON - UNII:N9E3X5056Q)	BORON	0.2 mg		
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	25 mg		

Inactive Ingredients			
Ingredient Name	Strength		
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)			
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)			
CALCIUM PHO SPHATE, DIBASIC, ANHYDRO US (UNII: L11K75P92J)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)			
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
TALC (UNII: 7SEV7J4R1U)			
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)			
HYPROMELLOSES (UNII: 3NXW29V3WO)			
TRIACETIN (UNII: XHX3C3X673)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			

Pacl	kaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1 NHRIC:73317-1050-9	90 in 1 BOTTLE			
<b>Marketing Infor</b>	mation			
Marketing Category	Application Number or Monograp	ph Citation	Marketing Start Date	Marketing End Date
DIETA DV CLIDDI EMENIT			02/03/2020	
DIETARY SUPPLEMENT			02/03/2020	

Supplement F	acts	
Serving Size:		Serving per Container :
	<b>Amount Per Serving</b>	% Daily Value
color		
scoring	1	
shape		
size (solid drugs)	5 mm	

# **Labeler -** SLV PHARMACEUTICALS LLC DBA AUM PHARMACEUTICALS (081225162)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
SLV PHARMACEUTICALS LLC DBA AUM PHARMACEUTICALS		081225162	repack(73317-1050)	

Revised: 2/2020 SLV PHARMACEUTICALS LLC DBA AUM PHARMACEUTICALS