

**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**

**AvKARE, Inc.**

*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.*

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**Prenatal Plus Vitamin and Mineral Tablet**

Prenatal Plus Vitamin and Mineral Tablet is an Tan-Yellow colored, modified oval biconvex film coated tablet debossed G12 on one side, and provides 10 vitamins and 4 minerals to supplement the diet before, during and after pregnancy.

Each Prenatal Plus tablet Contains:

Vitamin A (Acetate and Beta Carotene) .....	4000 I.U.
Vitamin C (Ascorbic acid).....	120 mg
Vitamin D-3 (Cholecalciferol).....	400 I.U.
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(Niacinamide).....	20 mg
Vitamin B-6 (Pyridoxine HCl).....	10 mg
Folic Acid.....	1 mg
Vitamin B-12 (Cyanocobalamin).....	12 mcg
Calcium (Calcium Carbonate).....	200 mg
Iron (Ferrous Fumarate).....	27 mg
Zinc (Zinc Oxide).....	25 mg
Copper (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

**Indication**

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

### **Dosage**

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

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.

This product contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

STORE AT CONTROLLED ROOM TEMPERATURE 15<sup>0</sup> - 30<sup>0</sup>C (59<sup>0</sup> - 86<sup>0</sup>F). AVOID EXCESS HEAT.

Dispense in a well closed light-resistant container, with a child resistant container.

Vitamin and Mineral  
Tablet

Multi-Vitamin

Rx Only                    100 Tablets

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN

DO NOT USE IF INNER SAFETY SEAL IS BROKEN OR MISSING.

Questions or comments call 1-855-361-3993

Manufactured For:  
AvKARE, Inc.  
Pulaski, TN 38478

Mfg.Rev. 09/12    AV Rev. 07/17 (P)

STORE AT CONTROLLED ROOM TEMPERATURE  
15° to 30°C (59° to 86°F). AVOID EXCESS  
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Dispense in a well closed, light-resistant  
container, with a child resistant cap.

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**MINERAL S:**

Calcium (Calcium Carbonate) ..... 200 mg  
Iron (Ferrous Fumarate) ..... 27 mg  
Zinc (Zinc Oxide) ..... 25 mg  
Copper (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,  
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NDC 42291-686-01

# Prenatal Plus Vitamin and Mineral Tablet

Multi-Vitamin

100 Tablets

Rx Only

**Each Tablet Contains:**

**VITAMINS:**

	Amount Per Tablet
Vitamin A (as 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 (Niacinamide) .....	20 mg
Vitamin B-6 (as Pyridoxine HCl) .....	10 mg
Folic Acid .....	1 mg
Vitamin B-12 (Cyanocobalamin) .....	12 mcg

Peel  
Here

NDC 42291-686-01

## Prenatal Plus

Vitamin and Mineral  
Tablet

Multi-Vitamin

100 Tablets      Rx Only

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN

DO NOT USE IF INNER SAFETY SEAL IS BROKEN OR MISSING.

Manufactured For: AvKARE, Inc.  
Pulaski, TN 38478

Prenatal Plus Vitamin and Mineral Tablet (100 Tablets)

Mfg. Rev. 09/12

AV Rev. 07/17 (P)

### 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

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:42291-686(NDC:65162-668)
<b>Route of Administration</b>	ORAL		

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VITAMIN A ACETATE (UNII: 3LE3D9D6OY) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	3080 [iU]
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	12 ug
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	120 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	400 [iU]
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
THIAMINE MONONITRATE (UNII: 8K0I04919X) (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
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	22 mg
.BETA.-CAROTENE (UNII: 01YAE03M7J) (.BETA.-CAROTENE - UNII:01YAE03M7J)	.BETA.-CAROTENE	920 [iU]
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	25 mg
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	200 mg
FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	27 mg

<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	10 mg
<b>CUPRIC OXIDE</b> (UNII: V1XJQ704R4) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	2 mg

### Inactive Ingredients

Ingredient Name	Strength
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CROSCARMELLOSE 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)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM ASCORBATE (UNII: S033EH8359)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBIC ACID (UNII: X045WJ989B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCROSE (UNII: C151H8M554)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

### Product Characteristics

<b>Color</b>	yellow (Tan-Yellow)	<b>Score</b>	no score
<b>Shape</b>	OVAL (Modified Oval Biconvex)	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	G12
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42291-686-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/19/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/11/2012	

**Labeler** - AvKARE, Inc. (796560394)

Revised: 1/2020

AvKARE, Inc.