

**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  
AvPAK**

*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**

**Multi-Vitamin Prenatal / Postnatal  
Dietary Supplement**

**Rx Only**

**DESCRIPTION**

Prenatal Plus Vitamin and Mineral Tablet is an orally administered prenatal / postnatal prescription dietary supplement for both lactating and non-lactating mothers and should be administered under the supervision of a licensed medical practitioner.

**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**

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.

Call your licensed medical practitioner about side effects.

To report a serious adverse event or obtain product information, contact AvKARE at 1-855-361-3993; email [drugsafety@avkare.com](mailto:drugsafety@avkare.com)

## DOSAGE AND ADMINISTRATION

Before, during and/or after pregnancy, one tablet daily with a meal, or as directed by a licensed medical practitioner.

## HOW SUPPLIED

Prenatal Plus Vitamin and Mineral Tablets are beige colored tablets, debossed with "677" on one side, dispensed in bottles of 100 tablets (NDC 50268-677-01)

## Storage

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

**Protect from light and moisture. Dispense in a tight, light-resistant container with child-resistant closure.**

Manufactured for:

AvKARE

Pulaski, TN 38478

Rev. 11/2021

AV Rev. 11/2021

## PRINCIPAL DISPLAY PANEL

**AVKARE**  
50268-677-01

**Prenatal Plus Vitamin and Mineral Tablet**  
Multi-Vitamin Prenatal/Postnatal Dietary Supplement

**TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.**

Rx  
100 Tablets

	Amount Per Serving	% Daily Value for pregnant and Lactating Women †
Vitamin A (as Acetate and Beta Carotene)	1200 mcg	92%
Vitamin C (Ascorbic Acid)	120 mg	100%
Vitamin D (Vitamin D3 as cholecalciferol)	10 mcg (400IU)	67%
Vitamin E (dl-Alpha Tocopheryl Acetate)	9.9 mg	52%
Thiamin (Vitamin B1 from Thiamine Mononitrate)	1.84 mg	131%
Riboflavin (Vitamin B2)	3 mg	188%
Niacin (Niacinamide)	20 mg	111%
Vitamin B6 (as Pyridoxine HCl)	10 mg	500%
Folate	1700 mcg DFE (1 mg Folic Acid)	283%
Vitamin B12 (Cyanocobalamin)	12 mcg	429%
Calcium (Calcium Carbonate)	200 mg	15%
Iron (Ferrous Fumarate)	27 mg	100%
Zinc (Zinc Oxide)	25 mg	192%
Copper (Cupric Oxide)	2 mg	154%

† Percent Daily Value (DV) based on a 2,000 calorie diet.

Other Ingredients: Microcrystalline Cellulose, Croscarmellose Sodium, Stearic Acid, Magnesium Stearate, Silicon Dioxide, Coating (Talc Powder, Carnauba Wax, Polyethylene Glycol, Polyvinyl Alcohol, Talc, Titanium Dioxide).

**DESCRIPTION:** Prenatal Plus Vitamin and Mineral Tablet is an orally administered prenatal/postnatal prescription dietary supplement for both lactating and non-lactating mothers and should be administered under the supervision of a licensed medical practitioner.

**DIRECTIONS:** Before, during and/or after pregnancy, one tablet daily with a meal, or as 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 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 Controlled Room Temperature 15° – 30°C (59° – 86°F). Protect from light and moisture. Dispense in a light, light-resistant container with child-resistant closure.

Call your licensed medical practitioner about side effects.

To report a serious adverse event or obtain product information, contact AvKare at 1-855-361-3983; email [drugsafety@avkare.com](mailto:drugsafety@avkare.com)

Prenatal Plus Vitamin and Mineral Tablets are beige colored tablets, debossed with "677" on one side, dispensed in bottles of 100 tablets.

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Rev. 11/2021 AV Rev. 11/2021

## 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:50268-677
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Route of Administration ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	9.9 mg
<b>VITAMIN A ACETATE</b> (UNII: 3LE3D9D6OY) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	3080 [iU]
<b>BETA CAROTENE</b> (UNII: 01YAE03M7J) (BETA CAROTENE - UNII:01YAE03M7J)	BETA CAROTENE	920 [iU]
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	120 mg
<b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	400 [iU]
<b>THIAMINE MONONITRATE</b> (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.84 mg
<b>RIBOFLAVIN</b> (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	3 mg
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	20 mg
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	10 mg
<b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
<b>CYANOCOBALAMIN</b> (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	12 ug
<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	200 mg
<b>FERROUS FUMARATE</b> (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	27 mg
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	25 mg
<b>CUPRIC OXIDE</b> (UNII: V1XJQ704R4) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	2 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>ASCORBYL PALMITATE</b> (UNII: QN83US2B0N)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE</b> (UNII: O7TSZ97GEP)	
<b>.ALPHA.-TOCOPHEROL, DL-</b> (UNII: 7QWA1RIO01)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6130)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM ASCORBATE</b> (UNII: S033EH8359)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBIC ACID</b> (UNII: X045WJ989B)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	

**TITANIUM DIOXIDE** (UNII: 15FIX9V2JP)

**TRIACETIN** (UNII: XHX3C3X673)

### Product Characteristics

<b>Color</b>	gray (Beige)	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	677
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50268-677-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/16/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/16/2022	

**Labeler** - AvPAK (832926666)

Revised: 4/2022

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