

**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](#).

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

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 (Beet 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

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

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:50268-677
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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: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	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: R5L488RY0Q) (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)	
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: 70097M6130)	
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	gray (Beige)	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	677
Contains			

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: 3/2022

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