

PNV PRENATAL VITAMIN PLUS VITAMIN A- .alpha.-tocopherol acetate, dl-, ascorbic acid, cholecalciferol, cyanocobalamin, folic acid, ferrous fumarate, calcium phosphate, dibasic, anhydrous, niacinamide, pyridoxine hydrochloride, riboflavin, thiamine mononitrate, and vitamin a acetate tablet

Sancilio & Company 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.

PNV Prenatal Health™ - Prenatal Vitamins

PNV tablets are formulated to provide vitamin and mineral supplementation throughout pregnancy and during the postnatal period, for both lactating and non-lactating mothers, and is useful for improving nutritional status prior to conception.

Each PNV tablet contains:

VITAMINS:

Vitamin A (as acetate)	2500 IU
Vitamin C (as Ascorbic Acid)	60 mg
Vitamin D3 (as Cholecalciferol)	400 IU
Vitamin E (as Tocopheryl acetate)	15 IU
Vitamin B1 (as Thiamine Mononitrate)	1.05 mg
Vitamin B2 (as Riboflavin, USP)	1.2 mg
Niacin (as Niacinamide)	13.5 mg
Vitamin B6 (as Pyridoxine HCL)	1.05 mg
Folic Acid	1 mg
Vitamin B12 (as Cyanocobalamin)	4.5 mcg

MINERAL:

Iron (as ferrous fumarate)	27 mg
Calcium (as Dibasic Calcium Phosphate)	50 mg

OTHER INGREDIENTS

Microcrystalline Cellulose, Croscarmellose Sodium, Citric Acid, Talc and Magnesium Stearate.

DIRECTIONS

One tablet daily with a meal, or as directed by a physician.

CAUTION

Folic acid may partially correct the hematological damage due to vitamin B12 deficiency of pernicious anemia, while the associated neurological damage progresses.

WARNING

Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of the reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

ADVERSE REACTIONS

In some cases, allergic hypersensitivity has been reported following administration of folic acid. Mild gastrointestinal disturbances may occur with products containing ferrous fumarate (iron), but usually subside with continuation of therapy.

STORE AT CONTROLLED ROOM TEMPERATURE 15°-30°C (59°-86°F). PROTECT FROM EXCESS HEAT AND MOISTURE. Dispense in a tight, light-resistant container with child-resistant closure.

This medical food product is formulated to be administered orally, under the supervision of a physician and is intended for the management of a dietary deficiency of folic acid and iron for which a distinctive nutritional requirement, based on recognized scientific principles, has been established by medical evaluation. The numeric identifier on this product's labeling is an assigned product code for use with pharmacy-level, health insurance and state level reimbursement programs and is not intended to denote registration or approval from the FDA.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

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

Manufactured by: **Sancilio & Company, Inc.**,
Riviera Beach, FL 33404
(800) SCI-8711

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REV: 12/07/12

PRINCIPAL DISPLAY PANEL - 400 Tablet Bottle Label

44946-1046-4

Rx only

PNV Prenatal Health

PNV

Prenatal Vitamins

FOLIC ACID + IRON

MULTIVITAMIN

PLUS VITAMIN A

Tablets

**Provides vitamin and
mineral supplementation
throughout pregnancy
and postnatal period**

Sugar & Gluten Free

SCI

Sancilio & Company, Inc

Developing good science into great medicine

400

TABLETS

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LOT/EXP

NO VARNISH



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Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:44946-1046
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
.Alpha.-Tocopherol Acetate, DL- (UNII: WR1WPI7EW8) (.Alpha.-Tocopherol, DL - UNII:7QWA1RIO01)	.Alpha.-Tocopherol, DL-	15 [iU]
Ascorbic Acid (UNII: PQ6CK8PD0R) (Ascorbic Acid - UNII:PQ6CK8PD0R)	Ascorbic Acid	60 mg
Cholecalciferol (UNII: 1C6V77QF41) (Cholecalciferol - UNII:1C6V77QF41)	Cholecalciferol	400 [iU]
Cyanocobalamin (UNII: P6YC3EG204) (Cyanocobalamin - UNII:P6YC3EG204)	Cyanocobalamin	4.5 ug
Folic Acid (UNII: 935E97BOY8) (Folic Acid - UNII:935E97BOY8)	Folic Acid	1 mg
Ferrous fumarate (UNII: R5L488RY0Q) (Ferrous cation - UNII:GW895810WR)	Ferrous cation	27 mg
Calcium Phosphate, Dibasic, Anhydrous (UNII: L11K75P92J) (CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS - UNII:L11K75P92J)	Calcium Phosphate, Dibasic, Anhydrous	50 mg
Niacinamide (UNII: 25X51I8RD4) (Niacinamide - UNII:25X51I8RD4)	Niacinamide	13.5 mg
Pyridoxine Hydrochloride (UNII: 68Y4CF58BV) (Pyridoxine - UNII:KV2JZ1BI6Z)	Pyridoxine Hydrochloride	1.05 mg
Riboflavin (UNII: TLM2976OFR) (Riboflavin - UNII:TLM2976OFR)	Riboflavin	1.2 mg
Thiamine Mononitrate (UNII: 8K0I04919X) (Thiamine Ion - UNII:4ABT0J945J)	Thiamine	1.05 mg
Vitamin A Acetate (UNII: 3LE3D9D6OY) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	2500 [iU]

Inactive Ingredients

Ingredient Name	Strength
Cellulose, Microcrystalline (UNII: OP1R32D61U)	

Croscarmellose sodium (UNII: M28OL1HH48)

Anhydrous Citric Acid (UNII: XF417D3PSL)

Talc (UNII: 7SEV7J4R1U)

Magnesium stearate (UNII: 70097M6I30)

Product Characteristics

Color	BROWN (Light brown to brown-speckled)	Score	no score
Shape	OVAL (capsule-shaped)	Size	18mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44946-1046-0	30 in 1 BOTTLE, PLASTIC		
2	NDC:44946-1046-2	90 in 1 BOTTLE, PLASTIC		
3	NDC:44946-1046-4	400 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		12/07/2012	

Labeler - Sancilio & Company Inc (176681257)

Revised: 12/2012

Sancilio & Company Inc