PNV PRENATAL VITAMIN- .alpha.-tocopherol acetate, dl-, cholecalciferol, cyanocobalamin, ferrous fumarate, folic acid, niacinamide, sodium ascorbate, ascorbic acid, pyridoxine hydrochloride, riboflavin, and thiamine mononitrate tablet, chewable Sancilio & Company Inc

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## PNV Prenatal Health<sup>TM</sup> - Prenatal Vitamins

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

## Each fruit-flavored PNV Chewable tablet contains:

120 mg
400 IU
11 IU
2 mg
3 mg
20 mg
10 mg
1 mg
12 mcg
29 mg

### **OTHER INGREDIENTS**

Microcrystalline cellulose, xylitol, magnesium stearate, talc, natural fruit flavor, malic acid, sucralose, citric acid, and mixed tocopherols.

### **DIRECTIONS**

One tablet daily with a meal, or as directed by a physician. Tablets should be chewed or crushed before swallowing.

## **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.

#### **HOW SUPPLIED**

**PNV** Prenatal Health™ - Prenatal Vitamins are light brown to brown-speckled, fruit-flavored, round tablets debossed "SCI" on one side.

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: 12/06/11

## PRINCIPAL DISPLAY PANEL - 90 Tablets Bottle Label

44946-1041-5

PNV Prenatal Health **PNV**Prenatal Vitamins

FOLIC ACID + IRON MULTIVITAMIN Chewable Tablets

Dispense under a physician's order<sup>†</sup>

**Dietary Supplement** 

Sugar Free

SCI

Sancilio & Company, Inc

Developing Good Science into Great Medicine

90

**TABLETS** 

## PW Prenatal Health™ - Prenatal Vitamins

PMV chewable 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.‡ DIRECTIONS: One tablet daily with a meal, or as directed by a physician. Tablets should be chewed or crushed before swallowing.

**TAMPER EVIDENT FEATURE:** Do not use if inner-seal beneath cap is missing or broken.

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.

**CAUTION:** Folic Acid may mask the symptoms of hematological damage due to Vitamin B12 deficiency of pernicious anemia while the associated neurological damage progresses.

Other Information: You may report serious side effects to 1-800-SCI-8711. 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.

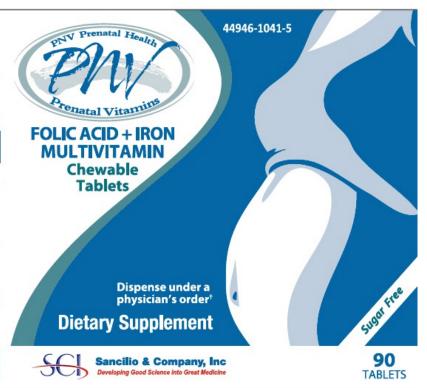
IF OVERDOSAGE IS SUSPECTED, SEEK PROFESSIONAL ASSISTANCE

IF OVERDOSAGE IS SUSPECTED, SEEK PROFESSIONAL ASSISTANCE OR CONTACT A POISON CONTROL CENTER IMMEDIATELY 1-800-222-1222.

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 with the FDA.

'The manufacturer of this product requires that it be dispensed only under the order of a physician or licensed medical practitioner.

\*THESE STATEMENTS HAVE NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE OR PREVENT ANY DISEASE.





## PNV PRENATAL VITAMIN

.alpha.-tocopherol acetate, dl-, cholecalciferol, cyanocobalamin, ferrous fumarate, folic acid, niacinamide, sodium ascorbate, ascorbic acid, pyridoxine hydrochloride, riboflavin, and thiamine mononitrate tablet, chewable

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Product Type DIETARY SUPPLEMENT Item Code (Source) NHRIC:449 46-1041

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
.AlphaTocopherol Acetate, DL- (UNII: WR1WPI7EW8) (.AlphaTocopherol, DL UNII:7QWA1RIO01)	.AlphaTocopherol, DL-	11 [iU]			
Cholecalciferol (UNII: 1C6V77QF41) (Cholecalciferol - UNII:1C6V77QF41)	Cholecalciferol	400 [iU]			
Cyanocobalamin (UNII: P6 YC3EG204) (Cyanocobalamin - UNII:P6 YC3EG204)	Cyanocobalamin	12 ug			
Ferrous fumarate (UNII: R5L488RY0Q) (Ferrous cation - UNII:GW89581OWR)	Ferrous cation	29 mg			
Folic Acid (UNII: 935E97BOY8) (Folic Acid - UNII:935E97BOY8)	Folic Acid	1 mg			
Niacinamide (UNII: 25X5118RD4) (Niacinamide - UNII:25X5118RD4)	Niacinamide	20 mg			
Sodium Ascorbate (UNII: S033EH8359) (Ascorbic Acid - UNII:PQ6CK8PD0R)	Ascorbic Acid	60 mg			
Ascorbic Acid (UNII: PQ6CK8PD0R) (Ascorbic Acid - UNII:PQ6CK8PD0R)	Ascorbic Acid	60 mg			
Pyridoxine Hydrochloride (UNII: 68 Y4CF58BV) (Pyridoxine - UNII:KV2JZ1BI6Z)	Pyridoxine	10 mg			
Riboflavin (UNII: TLM2976OFR) (Riboflavin - UNII:TLM2976OFR)	Ribo fla vin	3 mg			
Thiamine Mononitrate (UNII: 8K0I04919X) (Thiamine Ion - UNII:4ABT0J945J)	Thiamine	2 mg			

Inactive Ingredients					
Ingredient Name	Strength				
Xylitol (UNII: VCQ006KQ1E)					
Microcrystalline Cellulose (UNII: OP1R32D61U)					
Malic Acid (UNII: 817L1N4CKP)					
Talc (UNII: 7SEV7J4R1U)					
Magnesium stearate (UNII: 70097M6I30)					
Sucralose (UNII: 96K6UQ3ZD4)					
Anhydrous Citric Acid (UNII: XF417D3PSL)					
Tocopherol (UNII: R0ZB2556P8)					

Packaging					
#	Item Code	Package Description	Marketing Start Date	<b>Marketing End Date</b>	
1	NHRIC:44946-1041-5	90 in 1 BOTTLE, PLASTIC			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
DIETARY SUPPLEMENT		12/20/2011			

Supplement Facts				
Serving Size :	<b>Serving per Container:</b>			
Amount Pe	r Serving % Daily Value			
color				
scoring 1				

shape
size (solid drugs) 16 mm
imprint
flavor

# Labeler - Sancilio & Company Inc (176681257)

Revised: 12/2017 Sancilio & Company Inc