

ZATEAN-PN PLUS- levomefolate calcium, folic acid, ascorbic acid, cholecalciferol, .alpha.-tocopherol, pyridoxine, cyanocobalamin, biotin, calcium carbonate, ferrous fumarate, potassium iodide, magnesium oxide, doconexent, and icosapent capsule
Trigen Laboratories, LLC

Zatean™-Pn Plus
Softgels

SUPPLEMENT FACTS

Supplement Facts

Serving Size: 1 Softgel Capsule

Servings Per Container: 30

	Amount Per Serving	% DV for Pregnant and Lactating Women
Calories	10	
Total Fat	0.5 g	<1%**
Vitamin C (Ascorbic Acid)	85 mg	71%
Vitamin D (as Cholecalciferol)	5 mcg (200 IU)	33%
Vitamin E (as d-Alpha Tocopheryl Acetate)	7 mg* (10 IU)	37%
Vitamin B₆ (as Pyridoxine HCl)	25 mg	1250%
Folate (as L-Methylfolate (6S)-5-MTHF) 600 mcg and Folic Acid 400 mcg)	1667 mcg DFE	278%
Vitamin B₁₂ (as Cyanocobalamin)	12 mcg	429%
Biotin	250 mcg	714%
Calcium (as Calcium Carbonate)	140 mg	11%
Iron (as Ferrous Fumarate)	28 mg	104%
Iodine (as Potassium Iodide)	150 mcg	52%
Magnesium (as Magnesium Oxide)	45 mg	11%
DHA (Docosahexaenoic Acid)	300 mg	†
EPA (Eicosapentaenoic Acid)	40 mg	†
† Daily Value (DV) not established		
*Equal to mg Alpha-Tocopherol		
** Percent Daily Values are based on a 2,000 calorie diet		

Other Ingredients: Orange Cream Flavor O.S., Citric Acid, Biomin Potassium Citrate, Soy Lecithin, Yellow Beeswax

Shell Ingredients: Bovine Gelatin, Glycerin, Purified Water, Sorbitol, Titanium Dioxide, Ethyl Vanillin, FD&C Yellow #5, FD&C Blue #1, and Caramel.

THIS PRODUCT CONTAINS SOY AND FISH OIL (ANCHOVY).

Zatean™-Pn Plus is a prescription prenatal/postnatal multivitamin/ mineral softgel with an essential fatty acid and is indicated for the supplemental requirements of patients with nutritional deficiencies or are in

need of nutritional supplementation.

CONTRAINDICATIONS

This product is contraindicated in patients with a known hypersensitivity to any of the ingredients including soy or fish oil.

WARNING

Administration of omega-3 fatty acids – including DHA, should be avoided in patients with inherited or acquired bleeding diatheses, including those taking anticoagulants.

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.

PRECAUTIONS

General: Folic acid alone is an improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B12 is deficient. Folic acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurologic manifestations remain progressive. Reduced folates may be less likely than folic acid to mask vitamin B12 deficiency. Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

The patient's medical conditions and consumption of other drugs, herbs, and/or supplements should be considered.

Biotin levels higher than the recommended daily allowance may cause interference with some laboratory tests, including cardiovascular diagnostic tests (e.g. troponin) and hormone tests, and may lead to incorrect test results. Tell your healthcare provider about all prescription and over-the-counter medicines, vitamins, and dietary supplements that you take, including biotin.

This product contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible patients. 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.

DRUG INTERACTIONS

Pyridoxine hydrochloride should not be given to patients receiving the drug levodopa, because the action of levodopa is antagonized by pyridoxine hydrochloride. However, pyridoxine hydrochloride may be used concurrently in patients receiving a preparation containing both carbidopa and levodopa.

There is a possibility of increased bleeding due to pyridoxine interaction with anticoagulants (e.g., Aspirin, Heparin, Clopidogrel).

ADVERSE REACTIONS

Allergic sensitization has been reported following both oral and parenteral administration of folic acid, as well as possibly the use of other forms of folates, including reduced folates. Paresthesia, somnolence, nausea and headaches have been reported with pyridoxine hydrochloride. Mild transient diarrhea, polycythemia vera, itching, transitory exanthema and the feeling of swelling of the entire body have been associated with cyanocobalamin.

DESCRIPTION

Zatean™ - Pn Plus is an oblong shaped, dark green soft gelatin capsule containing brown paste with white "T582" laser etched.

DIRECTIONS FOR USE

Take one softgel capsule by mouth daily or as prescribed by a physician.

HOW SUPPLIED

Zatean™ - Pn Plus is available in bottles of 30 softgel capsules.

PRODUCT CODE 13811-582-30

STORAGE

Store at 20°-25°C (68°-77°F), excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature].

KEEP OUT OF REACH OF CHILDREN.

For use on the order of a healthcare practitioner.

Call your doctor about side effects. To report side effects, call Trigen Laboratories, LLC at 1-877-482-3788 or FDA at 1-800-FDA-1088.

Rev. 09/2019

Customer Service: 1-877-482-3788

**Manufactured for:
Trigen Laboratories, LLC
Bridgewater, NJ 08807
www.trigenlab.com**

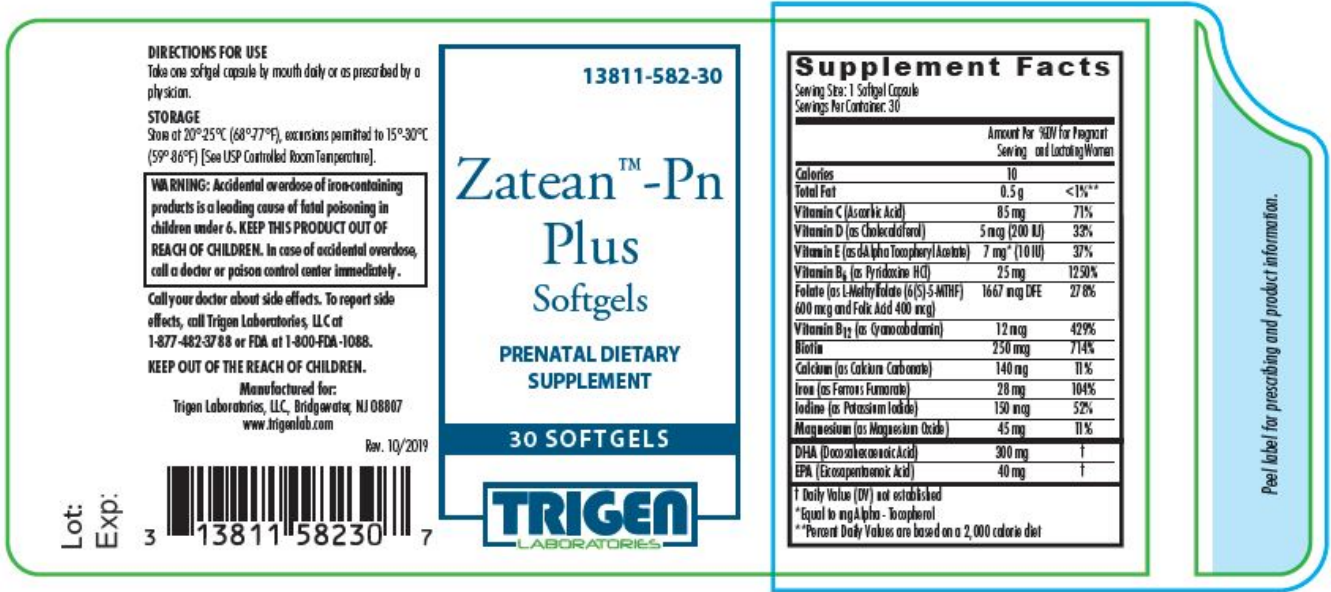


PRINCIPAL DISPLAY PANEL - 30 Softgel Bottle Label

13811-582-30

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Plus
Softgels**

30 SOFTGELS



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13811-582-30

Zatean™ -Pn
Plus
Softgels

PRENATAL DIETARY SUPPLEMENT

30 SOFTGELS

TRIGEN
 LABORATORIES

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Magnesium (as Magnesium Oxide)	45 mg	11%
DHA (Docosahexaenoic Acid)	90 mg	†
EPA (Eicosapentaenoic Acid)	40 mg	†

† Daily Value (DV) not established
 * Equal to mcg Alpha-Tocopherol
 ** Percent Daily Values are based on a 2,000 calorie diet

Lot:
 Exp:



Rev. 1Q/2019

Peel label for prescribing and product information.

ZATEAN-PN PLUS

levomefolate calcium, folic acid, ascorbic acid, cholecalciferol, .alpha.-tocopherol, pyridoxine, cyanocobalamin, biotin, calcium carbonate, ferrous fumarate, potassium iodide, magnesium oxide, doconexent, and icosapent capsule

Product Information			
Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:138 11-582
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
LEVOMEFOLIC ACID (UNII: 8S95DH25XC) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLIC ACID	600 ug	
folic acid (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	folic acid	400 ug	
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	85 mg	
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	200 [iU]	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1) (.ALPHA.-TOCOPHEROL - UNII:H4N855PNZ1)	.ALPHA.-TOCOPHEROL	10 [iU]	
PYRIDOXINE (UNII: KV2JZ1B16Z) (PYRIDOXINE - UNII:KV2JZ1B16Z)	PYRIDOXINE	25 mg	
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	12 ug	
Biotin (UNII: 6SO6U10H04) (Biotin - UNII:6SO6U10H04)	Biotin	250 ug	
calcium carbonate (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	calcium carbonate	140 mg	
ferrous fumarate (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW895810WR)	FERROUS CATION	28 mg	
potassium iodide (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	potassium iodide	150 ug	
magnesium oxide (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	magnesium oxide	45 mg	
Doconexent (UNII: ZAD9OKH9JC) (DOCONEXENT - UNII:ZAD9OKH9JC)	Doconexent	300 mg	
Icosapent (UNII: AAN7QOV9EA) (ICOSAPENT - UNII:AAN7QOV9EA)	Icosapent	40 mg	

Inactive Ingredients		
Ingredient Name		Strength

caramel (UNII: T9D99G2B1R)
ethyl vanillin (UNII: YC9ST449YJ)
FD&C Blue no. 1 (UNII: H3R47K3TBD)
FD&C Yellow no. 5 (UNII: I753WB2F1M)
gelatin (UNII: 2G86QN327L)
glycerin (UNII: PDC6A3C0OX)
lecithin, soybean (UNII: 1DI56QDM62)
water (UNII: 059QF0K00R)
sorbitol (UNII: 506T60A25R)
titanium dioxide (UNII: 15FIX9V2JP)
potassium citrate anhydrous (UNII: 86R1NVR0HW)
yellow wax (UNII: 2ZA36H0S2V)
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)
ORANGE OIL (UNII: AKN3KSD11B)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:13811-582-30	30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		05/01/2010	

Supplement Facts

Serving Size : **Serving per Container :**

	Amount Per Serving	% Daily Value
color		
imprint		
scoring	1	
shape		
size (solid drugs)	26 mm	

Labeler - Trigen Laboratories, LLC (830479668)