

PR NATAL 400 EC- beta carotene, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, calcium carbonate, iron protein succinylate, ferrous bisglycinate, magnesium oxide, zinc oxide, cupric oxide tablet
PruGen, Inc Pharmaceuticals

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.

PR Natal 400 ec

DESCRIPTION:

PR Natal 400 ec is a prescription regimen of prenatal multi-vitamin, multi-mineral, and omega-3 fatty acid supplements, supplied as tablets and softgel capsules.

INDICATIONS:

PR Natal 400 ec is a prescription regimen of prenatal multi-vitamin, multi-mineral, and omega-3 fatty acid supplements indicated for use in improving the nutritional status of women throughout pregnancy and in the post-natal period for both lactating and non-lactating mothers. PR Natal 400 ec is also useful in improving nutritional status prior to conception.

CONTRAINDICATIONS:

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

WARNINGS:

PRECAUTIONS:

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where Vitamin B12 is deficient. Since daily ingestion of more than 3 grams per day of omega-3 fatty acids (including alphanolenic acid (ALA), eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)) from fish oils may have potential antithrombotic activities and may increase bleeding times, administration of DHA should be avoided in patients with inherited or acquired bleeding diatheses, including those taking anticoagulants.

Folic acid especially in doses above 1.0 mg daily may obscure pernicious anemia (hematologic remission may occur while neurological manifestations remain progressive). Caution should be exercised to ensure that the prescribed dose of DHA does not exceed 1 gram (1,000 mg) per day.

WARNING:

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.

DRUG INTERACTIONS:

Pyridoxine supplements should be avoided in patients receiving levodopa alone, as the actions of levodopa may be antagonized.

ADVERSE REACTIONS:

Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

DOSAGE & ADMINISTRATION

Before, during and after pregnancy, one tablet and one softgel capsule taken by mouth daily, or as directed by a physician. The tablet and softgel capsule may be taken together or at different times of the day.

HOW SUPPLIED:

A 30-day supply of PR Natal 400 ec (NDC 42546-517-30) is supplied in 2 bottles with child-resistant caps. One bottle contains 30 pink-brown oval tablets imprinted with 'PE 669' on one side. A second bottle contains 30 frosted golden-colored oval enteric-coated DHA softgel capsules.

STORAGE:**DISPENSING:**

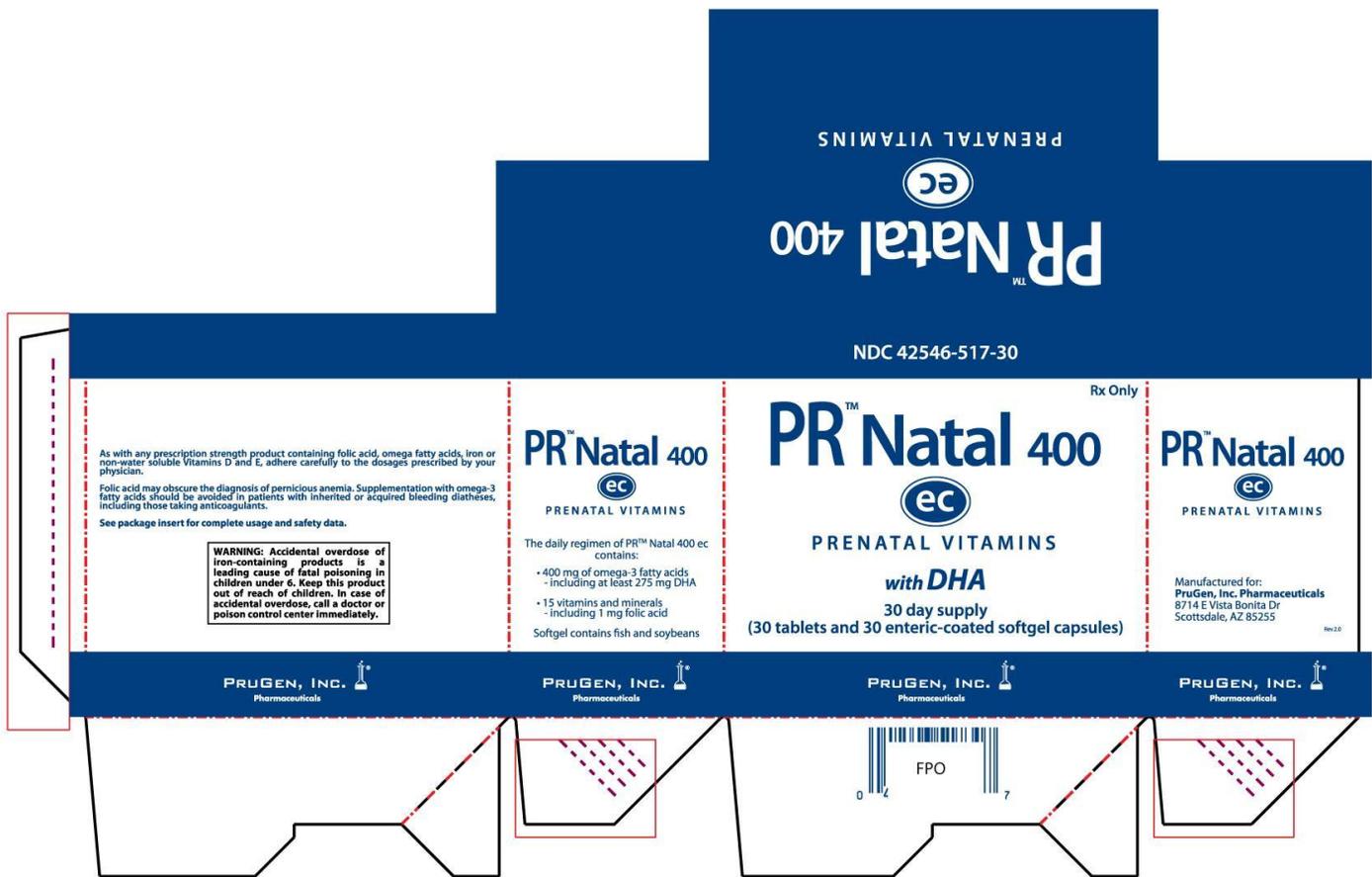
Store at controlled room temperature 20°-25°C (68°-77°F). Protect from moisture and excessive heat. Note that contact with moisture may produce surface discolorations of the tablet.

Keep in a well-closed, light-resistant container. Supplied in a child-resistant bottle as a safeguard against ingestion by children. **KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.**

Box Label

NDC 42546-517-30

PR Natal 400 ec



PR NATAL 400 EC

beta carotene, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, calcium carbonate, iron protein succinylate, ferrous bisglycinate, magnesium oxide, zinc oxide, cupric oxide tablet kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:42546-517
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42546-517-30	1 in 1 KIT		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	30
Part 2	1 BOTTLE	30

Part 1 of 2

PR NATAL 400 EC

beta carotene, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, calcium carbonate, iron protein succinylate, ferrous bisglycinate, magnesium oxide, zinc oxide, cupric oxide tablet tablet

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BETA CAROTENE (UNII: 01YAE03M7J) (BETA CAROTENE - UNII:01YAE03M7J)	BETA CAROTENE	3000 [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-	3 mg
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE ION	1.8 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	4 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	20 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1B16Z)	PYRIDOXINE	25 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	.012 mg
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	200 mg
IRON PROTEIN SUCCINYLATE (UNII: VBJ9L90P4L) (IRON PROTEIN SUCCINYLATE - UNII:VBJ9L90P4L)	IRON PROTEIN SUCCINYLATE	7.25 mg
FERROUS BISGLYCINATE HYDROCHLORIDE (UNII: IW3QLZ8MRC) (IRON - UNII:E1UOL152H7)	IRON	21.75 mg
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CATION	25 mg
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	25 mg
CUPRIC OXIDE (UNII: V1XJQ704R4) (CUPRIC OXIDE - UNII:V1XJQ704R4)	CUPRIC OXIDE	2 mg

Product Characteristics

Color	pink	Score	no score
Shape	capsule	Size	19mm
Flavor		Imprint Code	PE669
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/2010	

Part 2 of 2

PR NATAL 400 EC

omega 3 fatty acids capsule, gelatin coated

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OMEGA-3 FATTY ACIDS (UNII: 71M78END5S) (OMEGA-3 FATTY ACIDS - UNII:71M78END5S)	OMEGA-3 FATTY ACIDS	400 mg

Product Characteristics

Color	brown	Score	no score
Shape	capsule	Size	19mm
Flavor		Imprint Code	none
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
dietary supplement		01/01/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/2010	

Labeler - PruGen, Inc Pharmaceuticals (929922750)

Registrant - PruGen, Inc. Pharmaceuticals (929922750)

Establishment

Name	Address	ID/FEI	Business Operations
National Vitamin Company		102098324	manufacture(42546-517)

