

**SE-NATAL 19- .beta.-carotene, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, thiamine, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, calcium pantothenate, calcium carbonate, ferrous fumarate, zinc oxide and docusate sodium tablet
Seton 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.

Se-Natal 19 Tablets

Vitamins & Minerals with Folic Acid

R_x Only

DESCRIPTION

Se-Natal 19 is a white, oblong, film coated tablet, debossed "TL 019". Each film coated tablet contains:

Supplement Facts

Servings per Bottle: 100

Serving Size: 1 tablet

Each Tablet contains:

% DV for Pregnant and Lactating Women

Vitamin A (as beta carotene)	1000 IU	23%
Vitamin C (ascorbic acid)	100 mg	83%
Vitamin D (as cholecalciferol)	10 mcg	67%
Vitamin E (as dl-alpha tocoperol acetate)	30 IU	142%
Thiamine (Vitamin B ₁)	3 mg	214%
Riboflavin (Vitamin B ₂)	3 mg	188%
Niacin (as niacinamide)	15 mg	83%
Vitamin B ₆ (as pyridoxine HCl)	20 mg	1000%
Folate (folic acid)	1000 mcg	167%
Vitamin B ₁₂ (as cyanocobalamin)	12 mcg	429%
Pantothenic Acid (as calcium pantothenate)	7 mg	100%
Calcium (as calcium carbonate)	200 mg	15%
Iron (as ferrous fumarate)	29 mg	107%
Zinc (as zinc oxide)	20 mg	154%

OTHER INGREDIENTS

Acacia, Croscarmellose Sodium, Fumed Silica, Hypromellose, Magnesium Stearate, Microcrystalline Cellulose, Polyethylene Glycol, Polyvinyl Alcohol, Stearic Acid, Talc and Titanium Dioxide.

INDICATIONS

Se-Natal 19 tablets are indicated for use in improving the nutritional status of women throughout pregnancy and in the postnatal period for both lactating and non-lactating mothers. Se-Natal 19 tablets are also useful in improving the nutritional status of women prior to conception.

CONTRAINDICATIONS

This product is contraindicated in patients with a known hypersensitivity to any of the ingredients.

WARNINGS

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B₁₂ is deficient.

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

Take 2 hours after meals. Do not exceed recommended dose. Discontinue use if symptoms of intolerance appear.

Folic Acid

Folic acid in doses above 0.1 mg daily may obscure pernicious anemia, in that hematologic remission can occur while neurological manifestations remain progressive.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

Dosing for elderly patients should be cautious. Due to the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy, dosing should start at the lower end of the dosing range.

ADVERSE REACTIONS

Adverse reactions with iron therapy may include GI irritation, constipation, diarrhea, nausea, vomiting, and dark stools. Adverse reactions with iron therapy are usually transient. Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

DRUG INTERACTIONS

Prescriber should be aware of a number of iron/drug interactions, including antacids, tetracyclines, or fluoroquinolones.

OVERDOSAGE

Symptoms:

Abdominal pain, metabolic acidosis, anuria, CNS damage, coma, convulsions, death, dehydration, diffuse vascular congestion, hepatic cirrhosis, hypotension, hypothermia, lethargy, nausea, vomiting, diarrhea, tarry stools, melena, hematemesis, tachycardia, hyperglycemia, drowsiness, pallor, cyanosis, lassitude, seizures, and shock.

DOSAGE AND ADMINISTRATION

One tablet daily, or as directed by a physician.

NOTICE

Contact with moisture can discolor or erode the tablet. Do not chew tablet.

HOW SUPPLIED

Se-Natal 19 tablets for oral administration are supplied as white, coated, oblong tablets debossed "TL019", packaged in bottles of 100 tablets.

Product Code: 13925-116-01.

STORAGE

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

PHARMACIST

Dispense in a tight, light-resistant container as defined in the USP/NF with child-resistant closure.

Call your doctor about side effects. You may report side effects to FDA at 1-800-FDA-1088.

All prescriptions using this product shall be pursuant to state statutes as applicable. This is not an Orange Book product. This product may be administered only under a physician's supervision. There are no implied or explicit claims on therapeutic equivalence.

Reserved for Professional Recommendation.

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

R_x Only

Manufactured For:
Seton Pharmaceuticals
Manasquan, NJ 08736
1-800-510-3401

MADE IN CANADA

Code 116-01

Rev. 03/18

SETON PHARMACEUTICALS

PACKAGE LABEL. PRINCIPAL DISPLAY PANEL

NDC 13925-116-01

**Se-Natal 19
Tablets**

Vitamins and Minerals with Folic Acid

100 Tablets

R_x Only

**SETON
PHARMACEUTICALS**

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Call your doctor about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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Manufactured For:
Seton Pharmaceuticals, Wa, NJ 07719
1-800-510-3401

MADE IN CANADA 620421 Rev. 01/24

13925-116-01

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Tablets

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Vitamin E (as d- α -tocopheryl acetate)	30 IU 142%
Thiamine (Vitamin B1)	3 mg 214%
Riboflavin (Vitamin B2)	3 mg 188%
Niacin (as niacinamide)	15 mg 83%
Vitamin B6 (as pyridoxine HCl)	25 mg 1000%
Folate (folic acid)	1000 mcg 167%
Vitamin B12 (as cyanocobalamin)	12 mcg 425%
Pantothenic Acid (as calcium pantothenate)	7 mg 100%
Calcium (as calcium carbonate)	200 mg 15%
Iron (as ferrous fumarate)	29 mg 107%
Zinc (as zinc oxide)	20 mg 154%

Other Ingredients: Acacia, Croscarmellose, Docusate Sodium, Sodium, Fumed Silica, Hyramellose, Magnesium Stearate, Microcrystalline Cellulose, Polyethylene Glycol, Polyvinyl Alcohol, Stearic Acid, Talc and Titanium Dioxide.

DOSE AND ADMINISTRATION: One tablet daily or as directed by a physician. Do not chew tablet.

SE-NATAL 19

.beta.-carotene, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, thiamine, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, calcium pantothenate, calcium carbonate, ferrous fumarate, zinc oxide and docusate sodium tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:13925-116
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
.BETA.-CAROTENE (UNII: 01YAE03M7J) (.BETA.-CAROTENE - UNII:01YAE03M7J)	.BETA.-CAROTENE	1000 [iU]
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	100 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	400 [iU]
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	30 mg
THIAMINE (UNII: X66NSO3N35) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	3 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	3 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	15 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	20 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	12 ug
CALCIUM PANTOTHENATE (UNII: 568ET80C3D) (PANTOTHENIC ACID - UNII:19F5HK2737)	PANTOTHENIC ACID	7 mg
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	200 mg
FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	29 mg
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	20 mg
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	25 mg

Inactive Ingredients

Ingredient Name	Strength
ACACIA (UNII: 5C5403N260)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	TL019
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13925-116-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		07/01/2009	

Labeler - Seton Pharmaceuticals (828898002)

Registrant - Seton Pharmaceuticals (828898002)