

**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<sub>x</sub> 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 <sub>1</sub> )	3 mg	214%
Riboflavin (Vitamin B <sub>2</sub> )	3 mg	188%
Niacin (as niacinamide)	15 mg	83%
Vitamin B <sub>6</sub> (as pyridoxine HCl)	20 mg	1000%
Folate (folic acid)	1000 mcg	167%
Vitamin B <sub>12</sub> (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 B<sub>12</sub> 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<sub>x</sub> 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<sub>x</sub> Only**

**SETON  
PHARMACEUTICALS**

Store at 20° - 25°C (68° - 77°F), excursions permitted to 15° - 30°C (59° - 86°F) [See USP controlled room temperature].  
**KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.**

**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.

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

**Indications and Usage:** 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.

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

MADE IN CANADA L100193 Rev. 03/18

13925-116-01

**Se-Natal 19**  
Tablets

Vitamins and Minerals with Folic Acid

**100 Tablets**

R<sub>x</sub> Only

**DESCRIPTION:** Se-Natal 19 is a white, oblong, film coated tablet, debossed "11". Each film coated tablet contains:

Supplement Facts		
Servings per Bottle: 100	% DV for	
Serving Size: 1 tablet	Pregnant and	
Each Tablet contains:	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 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) .....	20 mg	1000%
Folate (folic acid) .....	1000 mcg	167%
Vitamin B12 (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, Docusate Sodium, Sodium, Fumed Silica, Hypromellose, 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

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

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>ACACIA</b> (UNII: 5C5403N26O)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYVINYL ALCOHOL</b> (UNII: 532B59J990)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	no score
--------------	-------	--------------	----------

<b>Shape</b>	CAPSULE	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	TL019
<b>Contains</b>			

### 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)

Revised: 6/2024

Seton Pharmaceuticals