

SE-NATAL 19 CHEWABLE- vitamins and minerals tablet, chewable **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 Chewable Tablets

A Prescription Prenatal Vitamin with other Vitamins and Minerals for Nutritional Supplementation

R_x Only

DESCRIPTION

Se-Natal 19 Chewable tablets are round, debossed "TL015." These tablets provide oil-soluble vitamins, water-soluble vitamins and minerals. Each tablet contains:

Supplement Facts		
Servings per Bottle:	100	%DV For Pregnant and Lactating Women
Serving Size	1 chewable tablet	
Each Tablet contains:		
Vitamin A (as beta carotene)	1000 IU	23%
Vitamin C (calcium ascorbate)	100 mg	83%
Vitamin D (as cholecalciferol)	10 mcg	67%
Vitamin E (as dl-alpha tocopherol 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%

CLINICAL PHARMACOLOGY

Oral iron is absorbed most efficiently when administered between meals. Iron is critical for normal hemoglobin synthesis to maintain oxygen transport, energy production and

proper function of cells. Adequate amounts of iron are necessary for effective erythropoiesis. Iron also serves as a cofactor of several essential enzymes, including cytochromes, which are involved in electron transport. Folic acid is required for nucleoprotein synthesis and the maintenance of normal erythropoiesis. Folic acid is the precursor of tetrahydrofolic acid, which is involved as a cofactor for transformylation reactions in the biosynthesis of purines and thymidylates of nucleic acids. Deficiency of folic acid may account for the defective deoxyribonucleic acid (DNA) synthesis that leads to megaloblast formation and megaloblastic macrocytic anemias. Vitamin B₁₂ is essential to growth cell reproduction, hematopoiesis, nucleic acid, and myelin synthesis. Deficiency may result in megaloblastic anemia or pernicious anemia.

OTHER INGREDIENTS

Acacia, Fumed Silica, Magnesium Stearate, Natural Orange Flavour, Orange Juice Powder, Stearic Acid, Stevia, Sucrose.

INDICATIONS AND USAGE

Se-Natal 19 Chewable 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 Chewable 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.

HOW SUPPLIED

Se-Natal 19 Chewable Tablets for oral administration are supplied as multi-color-speckled, round tablets debossed "TL015," packaged in bottles of 100 tablets.

Product Code: 13925-117-01

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/INF with child-resistant closure.

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

**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 117-01

Rev. 03/18

SETON PHARMACEUTICALS

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 13925-117-01

Se-Natal 19 Chewable Tablets

***A Prescription Prenatal Vitamin with other Vitamins and Minerals for
Nutritional Supplementation***

R_x Only

100 Tablets

SETON

PHARMACEUTICALS

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Indications and Usage: Se-Natal 19 chewable 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 chewable 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 L100194 Rev. 03/18



13925-117-01

Se-Natal 19 Chewable Tablets

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Vitamin E (as dl-alpha-tocopherol 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	629%
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, Fumed Silica, Magnesium Stearate, Natural Orange Flavour, Orange Juice Powder, Stearic Acid, Stevia, Sucrose.

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SE-NATAL 19 CHEWABLE

vitamins and minerals tablet, chewable

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:13925-117
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
.BETA.-CAROTENE (UNII: 01YAE03M7J) (.BETA.-CAROTENE - UNII:01YAE03M7J)	.BETA.-CAROTENE	1000 [iU]
CALCIUM ASCORBATE (UNII: 183E4W213W) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	100 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	400 [iU]
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WP1EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	30 [iU]
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	3 mg

RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	3 mg
NIACINAMIDE (UNII: 25X5118RD4) (NIACINAMIDE - UNII:25X5118RD4)	NIACINAMIDE	15 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	20 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

Inactive Ingredients

Ingredient Name	Strength
ACACIA (UNII: 5C5403N26O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
ORANGE JUICE (UNII: 5A9KE2L9L3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	BROWN	Score	no score
Shape	ROUND	Size	12mm
Flavor	ORANGE	Imprint Code	TL015
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13925-117-01	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)