

## **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.*

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### **Se-Natal 19 Chewable Tablets**

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

**R<sub>x</sub> 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:

| <b>Supplement Facts</b>                     |                   |   |
|---|-------------------|---|
| <b>Servings per Bottle:</b>                 | 100               | <b>%DV For Pregnant and Lactating Women</b> |
| <b>Serving Size</b>                         | 1 chewable tablet |   |
| <b>Each Tablet contains:</b>                |                   |   |
| 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 <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%  |

### **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 B<sub>12</sub> 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 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.

## **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<sub>x</sub> 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<sub>x</sub> Only**

**100 Tablets**

SETON

PHARMACEUTICALS

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**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 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.

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Seton Pharmaceuticals, Manasquan, NJ 08736  
1-800-510-3401

MADE IN CANADA L100194 Rev. 03/18



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13925-117-01

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**100 Tablets**

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## Supplement Facts

| Serving Size: 1 chewable tablet            | % DV for Pregnant and Lactating Women |       |
|--|---------------------------------------|-------|
| <b>Each Chewable Tablet contains:</b>      |                                       |       |
| 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-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

|                                |                         |                           |               |
|--------------------------------|-------------------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN PRESCRIPTION DRUG | <b>Item Code (Source)</b> | NDC:13925-117 |
| <b>Route of Administration</b> | ORAL                    |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength       | Strength  |
|--|-------------------------|-----------|
| <b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)                                  | FOLIC ACID              | 1 mg      |
| <b>.BETA.-CAROTENE</b> (UNII: 01YAE03M7J) (.BETA.-CAROTENE - UNII:01YAE03M7J)                        | .BETA.-CAROTENE         | 1000 [iU] |
| <b>CALCIUM ASCORBATE</b> (UNII: 183E4W213W) (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: WR1WP1EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01) | .ALPHA.-TOCOPHEROL, DL- | 30 [iU]   |
| <b>THIAMINE MONONITRATE</b> (UNII: 8K0I04919X) (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>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  |

### Inactive Ingredients

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

### Product Characteristics

|                 |        |                     |          |
|-----------------|--------|---------------------|----------|
| <b>Color</b>    | BROWN  | <b>Score</b>        | no score |
| <b>Shape</b>    | ROUND  | <b>Size</b>         | 12mm     |
| <b>Flavor</b>   | ORANGE | <b>Imprint Code</b> | TL015    |
| <b>Contains</b> |        |                     |          |

### 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<br>other |  | 07/01/2009           |                    |

**Labeler** - Seton Pharmaceuticals (828898002)