

**STROVITE ONE CAPLETS- vitamin a, calcium pantothenate, ascorbic acid, cholecalciferol, .alpha.-tocopherol succinate, d-, thiamine, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, biotin, cyanocobalamin, selenium, magnesium oxide, zinc oxide, cupric sulfate, manganese, chromium, .alpha.-lipoic acid, and lutein tablet
Exeltis USA, Inc.**

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.

STROVITE[®] ONE

0642-0207-90

STROVITE[®] ONE

**IRON FREE MULTIVITAMIN AND MINERAL
SUPPLEMENT**

Rx

COMPOSITION

Each caplet contains:

| | |
|--|------------------|
| Vitamin A (as beta carotene) | 900 mcg RAE |
| Vitamin C | 300 mg |
| Vitamin D (as cholecalciferol) | 25 mcg |
| Vitamin E (as d-alpha tocopheryl succinate) | 67 mg |
| Thiamin (as thiamine hydrochloride) | 20 mg |
| Riboflavin (vitamin B2) | 5 mg |
| Niacin (as niacinamide) | 25 mg NE |
| Vitamin B6 (as pyridoxine hydrochloride) | 25 mg |
| Folate (as folic acid) | 1,670 mcg DFE |
| Vitamin B12 (as cyanocobalamin) | 50 mcg |
| Biotin | 100 mcg |
| Pantothenic Acid (as calcium-D-pantothenate) | 15 mg |
| Magnesium (as magnesium oxide) | 50 mg |
| Zinc (as zinc oxide) | 25 mg |
| Selenium (as sodium selenate) | 100 mcg |
| Copper (as cupric sulfate) | 1.5 mg |
| Manganese (as manganese sulfate) | 1.5 mg |
| Chromium (as chromium chloride) | 50 mcg |

| | |
|-------------------|--------|
| Alpha Lipoic Acid | 7.5 mg |
| Lutein | 5 mg |

Other ingredients: Microcrystalline cellulose, dicalcium phosphate, hydroxypropyl methylcellulose, croscarmellose sodium, polyethylene glycol, titanium dioxide, talc, maltodextrin, modified food starch, sucrose, polyvinyl alcohol, stearic acid, silica, magnesium stearate, corn oil, starch, vitamin E alcohol, sodium ascorbate, mannitol.

INDICATIONS AND USAGE

STROVITE[®] ONE is indicated to provide nutritional supplementation to support optimum vitamin and mineral levels.

CONTRAINDICATIONS

STROVITE[®] ONE is contraindicated in patients with hypersensitivity to any of its components. Folic Acid is contraindicated in patients with untreated and uncomplicated pernicious anemia, and in those with anaphylactic sensitivity to folic acid.

Cyanocobalamin is contraindicated in patients with sensitivity to cobalt or to cyanocobalamin (Vitamin B12).

WARNING/PRECAUTIONS

Vitamin D supplementation should be used with caution in those with hypercalcemia or conditions that may lead to hypercalcemia such as hyperparathyroidism and those who form calcium-containing kidney stones. High doses of vitamin D can lead to elevated levels of calcium that reside in the blood and soft tissues. Bone pain, high blood pressure, formation of kidney stones, renal failure, and increased risk of heart disease can occur.

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

The use of folic acid doses above 1 mg daily may precipitate or exacerbate the neurological damage of vitamin B12 deficiency.

Avoid overdose. Keep out of the reach of children.

Drug Interactions

High doses of folic acid may result in decreased serum levels of anticonvulsant drugs.

Vitamin D supplementation should not be given with large amounts of calcium in those with hypercalcemia or conditions that may lead to hypercalcemia such as hyperparathyroidism and those who form calcium-containing kidney stones.

Zinc can inhibit the absorption of certain antibiotics; take at least 2 hours apart to minimize interactions. Consult appropriate references for additional specific vitamin-drug interactions.

Information for Patients

Patients should be counseled to disclose all medical conditions, including use of all medications, vitamins and supplements, pregnancy, and breastfeeding.

Pediatric Use

Not recommended for pediatric use.

ADVERSE REACTIONS

Adverse reactions have been reported with specific vitamins and minerals, but generally at levels substantially higher than those in STROVITE[®] ONE.

DOSAGE AND ADMINISTRATION

One caplet daily or as directed by a physician.

HOW SUPPLIED

STROVITE[®] ONE is a white, oblong caplet, debossed EV0207; available in bottles of 90 caplets (0642-0207-90) and as professional samples (0642-0207-03).

Storage conditions: Store at room temperature 15°-30°C (59°-86°F). Avoid excessive heat and moisture.

Rx

MANUFACTURED IN THE USA

Distributed by:
Exeltis USA, Inc.
Florham Park, NJ 07932
1-877-324-9349
www.exeltisusa.com

©2022 Exeltis USA, Inc. All rights reserved.

US PATENT NO. 6,863,904
STROVITE[®] ONE is a trademark of Exeltis Healthcare S.L.

Rev. 10/2022 2079003-04

PRINCIPAL DISPLAY PANEL - 90 Caplet Bottle Label

0642-0207-90

Strovite[®] ONE

IRON FREE

MULTIVITAMIN

AND

MINERAL SUPPLEMENT

GLUTEN AND LACTOSE FREE

90 Caplets

Rx

| Supplement Facts | | |
|--|--------------------|---------------|
| Serving Size: 1 Caplet | | |
| Each caplet contains | Amount Per Serving | % Daily Value |
| Vitamin A (as beta carotene) | 900 mcg RAE | 100% |
| Vitamin C | 300 mg | 330% |
| Vitamin D3 (as cholecalciferol) | 25 mcg | 130% |
| Vitamin E (as d-alpha tocopheryl succinate) | 67 mg | 450% |
| Thiamin (as thiamine hydrochloride) | 20 mg | 1670% |
| Riboflavin (vitamin B2) | 5 mg | 390% |
| Niacin (as niacinamide) | 25 mg NE | 160% |
| Vitamin B6 (as pyridoxine hydrochloride) | 25 mg | 1470% |
| Folate (as folic acid) | 1,670 mcg DFE | 420% |
| Vitamin B12 (as cyanocobalamin) | 50 mcg | 2080% |
| Biotin | 100 mcg | 330% |
| Pantothenic Acid (as calcium-D-pantothenate) | 15 mg | 300% |
| Magnesium (as magnesium oxide) | 50 mg | 10% |
| Zinc (as zinc oxide) | 25 mg | 230% |
| Selenium (as sodium selenate) | 100 mcg | 180% |
| Copper (as cupric sulfate) | 1.5 mg | 170% |
| Manganese (as manganese sulfate) | 1.5 mg | 70% |
| Chromium (as chromium chloride) | 50 mcg | 140% |
| Alpha Lipoic Acid | 7.5 mg | * |
| Lutein | 5 mg | * |

* Daily Value not established.

Other ingredients: Microcrystalline cellulose, dicalcium phosphate, hydroxypropyl methylcellulose, croscarmellose sodium, polyethylene glycol, titanium dioxide, talc, maltodextrin, modified food starch, sucrose, polyvinyl alcohol, stearic acid, silica, magnesium stearate, corn oil, starch, vitamin E alcohol, sodium ascorbate, mannitol.

Rev. 10/2022 2079002-04

0642-0207-90

Strovite[®]ONE

IRON FREE
MULTIVITAMIN
AND
MINERAL SUPPLEMENT

GLUTEN AND LACTOSE FREE

90 Caplets

Rx

0642-0207-90 Lift Here

STROVITE[®]ONE

IRON FREE MULTIVITAMIN AND MINERAL SUPPLEMENT

Rx

INDICATIONS AND USAGE:
STROVITE[®] ONE is indicated to provide nutritional supplementation to support optimum vitamin and mineral levels.

CONTRAINDICATIONS:
STROVITE[®] ONE is contraindicated in patients with hypersensitivity to any of its components. Folic acid is contraindicated in patients with untreated and



STROVITE ONE CAPLETS

vitamin a, calcium pantothenate, ascorbic acid, cholecalciferol, .alpha.-tocopherol succinate, d-, thiamine, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, biotin, cyanocobalamin, selenium, magnesium oxide, zinc oxide, cupric sulfate, manganese, chromium, .alpha.-lipoic acid, and lutein tablet

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:0642-0207 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|----------------------------------|----------|
| MANGANESE (UNII: 42Z2K6ZL8P) (MANGANESE - UNII:42Z2K6ZL8P) | MANGANESE | 1.5 mg |
| VITAMIN A (UNII: 81G40H8B0T) (VITAMIN A - UNII:81G40H8B0T) | VITAMIN A | 900 ug |
| CALCIUM PANTOTHENATE (UNII: 568ET80C3D) (PANTOTHENIC ACID - UNII:19F5HK2737, CALCIUM CATION - UNII:2M83C4R6Z B) | PANTOTHENIC ACID | 7.5 mg |
| ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R) | ASCORBIC ACID | 300 mg |
| CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41) | CHOLECALCIFEROL | 25 ug |
| .ALPHA.-TOCOPHEROL SUCCINATE, D- (UNII: LU4B53JYVE) (.ALPHA.-TOCOPHEROL, D- - UNII:N9PR3490H9) | .ALPHA.-TOCOPHEROL SUCCINATE, D- | 45 ug |
| THIAMINE (UNII: X66NSO3N35) (THIAMINE ION - UNII:4ABT0J945J) | THIAMINE | 20 mg |
| RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR) | RIBOFLAVIN | 5 mg |
| NIACINAMIDE (UNII: 25X5118RD4) (NIACINAMIDE - UNII:25X5118RD4) | NIACINAMIDE | 25 mg |
| PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z) | PYRIDOXINE HYDROCHLORIDE | 25 mg |
| FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8) | FOLIC ACID | 1700 ug |

| | | |
|---|-------------------|--------|
| BIOTIN (UNII: 6S06U10H04) (BIOTIN - UNII:6S06U10H04) | BIOTIN | 100 ug |
| CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204) | CYANOCOBALAMIN | 50 ug |
| SELENIUM (UNII: H6241UJ22B) (SELENIUM - UNII:H6241UJ22B) | SELENIUM | 100 ug |
| MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838) | MAGNESIUM CATION | 50 mg |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 25 mg |
| CUPRIC SULFATE (UNII: LRX7AJ16DT) (CUPRIC CATION - UNII:8CBV67279L) | CUPRIC CATION | 1.5 mg |
| CHROMIUM (UNII: 0R0008Q3JB) (CHROMIUM - UNII:0R0008Q3JB) | CHROMIUM | 50 ug |
| ALPHA LIPOIC ACID (UNII: 73Y7P0K73Y) (ALPHA LIPOIC ACID - UNII:73Y7P0K73Y) | ALPHA LIPOIC ACID | 15 mg |
| LUTEIN (UNII: X72A60C9MT) (LUTEIN - UNII:X72A60C9MT) | LUTEIN | 5 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| GELATIN, UNSPECIFIED (UNII: 2G86QN327L) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| SOYBEAN OIL (UNII: 241ATL177A) | |
| TALC (UNII: 7SEV7J4R1U) | |
| SUCROSE (UNII: C151H8M554) | |
| ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J) | |
| ASCORBYL PALMITATE (UNII: QN83US2B0N) | |
| TOCOPHEROL (UNII: R0ZB2556P8) | |
| SODIUM ASCORBATE (UNII: S033EH8359) | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |
| .ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01) | |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|----------|
| Color | white | Score | no score |
| Shape | OVAL | Size | 19mm |
| Flavor | | Imprint Code | EV0207 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0642-0207-90 | 90 in 1 BOTTLE; Type 0: Not a Combination Product | 05/04/2001 | |
| 2 | NDC:0642-0207-03 | 1 in 1 BOX | 05/04/2001 | |
| 3 | | 3 in 1 BLISTER PACK; Type 0: Not a Combination | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| unapproved drug other | | 05/04/2001 | |

Labeler - Exeltis USA, Inc. (071170534)

Revised: 1/2023

Exeltis USA, Inc.