

**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.*

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**STROVITE® ONE**

**0642-0207-90**

**Iron Free Multivitamin and Mineral Supplement**

**Rx**

## **COMPOSITION**

Each caplet contains:

Vitamin C (as ascorbic acid)	300 mg
Vitamin D3 (as cholecalciferol)	1000 IU
Vitamin E (as d-alpha tocopheryl succinate)	100 IU
Vitamin B1 (as thiamine HCl)	20 mg
Vitamin B2 (as riboflavin)	5 mg
Niacinamide (Vitamin B3)	25 mg
Vitamin B6 (as pyridoxine HCl)	25 mg
Folic acid	1 mg
Vitamin B12 (as cyanocobalamin)	50 mcg
Biotin	100 mcg
Pantothenic Acid (as ca 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 chromic chloride)	50 mcg
Carotenoids (alpha-carotene, beta-carotene, cryptoxanthin, lutein, zeaxanthin)	3000 IU
Alpha Lipoic Acid	7.5 mg
Lutein	5 mg

**Other Ingredients:** Dibasic calcium phosphate, microcrystalline cellulose, carbohydrate, croscarmellose sodium, stearic acid, gelatin, polyvinyl alcohol, silicon dioxide, titanium dioxide (as color), polyethylene glycol, sucrose, magnesium stearate, modified food starch, soybean oil, talc, ethylcellulose, ascorbyl palmitate, mixed tocopherols, sodium ascorbate, medium chain triglycerides, dl-alpha-tocopherol.

**Contains: Soy**

## **INDICATIONS AND USAGE**

STROVITE<sup>®</sup> ONE is indicated to provide nutritional supplementation to support optimum vitamin and mineral levels.

## **CONTRAINDICATIONS**

STROVITE<sup>®</sup> 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 Over dosage. 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<sup>®</sup> 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).

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

Rx

### **Distributed by:**

**Exeltis USA, Inc.**

**Florham Park, NJ 07932**

1-877-324-9349

www.exeltisusa.com

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US Patent No. 6,863,904

Strovite® is a trademark of Exeltis USA, Inc.

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## **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**

0642-0207-90

**Strovite<sup>®</sup>ONE**

IRON FREE

MULTIVITAMIN  
AND  
MINERAL SUPPLEMENT

GLUTEN AND LACTOSE FREE

90 Caplets

Rx

0642-0207-90

Lift Here **STROVITE<sup>®</sup>ONE**  
IRON FREE MULTIVITAMIN AND MINERAL  
SUPPLEMENT  
Rx**INDICATIONS AND USAGE:**STROVITE<sup>®</sup> ONE is indicated to provide nutritional supplementation to support optimum vitamin and mineral levels.**CONTRAINDICATIONS:**STROVITE<sup>®</sup> 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 B<sub>12</sub>).**Supplement Facts**

Serving Size: 1 Caplet

Each caplet contains	Amount Per Serving	% Daily Value
Vitamin C (as ascorbic acid)	300 mg	500 %
Vitamin D <sub>3</sub> (as cholecalciferol)	1000 IU	250 %
Vitamin E (as d-alpha tocopheryl succinate)	100 IU	333 %
Vitamin B <sub>1</sub> (as thiamine HCl)	20 mg	1333 %
Vitamin B <sub>2</sub> (as riboflavin)	5 mg	294 %
Niacinamide (as vitamin B <sub>3</sub> )	25 mg	125 %
Vitamin B <sub>6</sub> (as pyridoxine HCl)	25 mg	1250 %
Folic Acid	1 mg	250 %
Vitamin B <sub>12</sub> (as cyanocobalamin)	50 mcg	833 %
Biotin	100 mcg	33 %
Pantothenic Acid (as Ca pantothenate)	15 mg	150 %
Magnesium (as magnesium oxide)	50 mg	12 %
Zinc (as zinc oxide)	25 mg	166 %
Selenium (as sodium selenate)	100 mcg	142 %
Copper (as cupric sulfate)	1.5 mg	75 %
Manganese (as manganese sulfate)	1.5 mg	75 %
Chromium (as chromic chloride)	50 mcg	41 %
Carotenoids (alpha-carotene, beta-carotene, cryptoxanthin, lutein, zeaxanthin)	3000 IU	*
Alpha Lipoic Acid	7.5 mg	*
Lutein	5 mg	*

\*\* Daily Value not established

Other Ingredients: Dibasic calcium phosphate, microcrystalline cellulose, carbohydrate, croscarmellose sodium, stearic acid, gelatin, polyvinyl alcohol, silicon dioxide, titanium dioxide (as color), polyethylene glycol, sucrose, magnesium stearate, modified food starch, soybean oil, talc, ethylcellulose, ascorbyl palmitate, mixed tocopherols, sodium ascorbate, medium chain triglycerides, d-alpha-tocopherol. **Contains: Soy**

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**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**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0642-0207
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Vitamin A</b> (UNII: 81G40H8B0T) (Vitamin A - UNII:81G40H8B0T)	Vitamin A	3000 [iU]
<b>Calcium Pantothenate</b> (UNII: 568ET80C3D) (Pantothenic Acid - UNII:19F5HK2737, Calcium Cation - UNII:2M83C4R6ZB)	Pantothenic Acid	7.5 mg
<b>Ascorbic Acid</b> (UNII: PQ6CK8PD0R) (Ascorbic Acid - UNII:PQ6CK8PD0R)	Ascorbic Acid	300 mg
<b>Cholecalciferol</b> (UNII: 1C6V77QF41) (Cholecalciferol - UNII:1C6V77QF41)	Cholecalciferol	1000 [iU]
<b>.Alpha.-Tocopherol Succinate, D-</b> (UNII: LU4B53JYVE) (.ALPHA.-TOCOPHEROL, D- - UNII:N9PR3490H9)	.Alpha.-Tocopherol Succinate, D-	100 [iU]
<b>Thiamine</b> (UNII: X66NSO3N35) (Thiamine Ion - UNII:4ABT0J945J)	Thiamine	20 mg
<b>Riboflavin</b> (UNII: TLM2976OFR) (Riboflavin - UNII:TLM2976OFR)	Riboflavin	5 mg
<b>Niacinamide</b> (UNII: 25X51I8RD4) (Niacinamide - UNII:25X51I8RD4)	Niacinamide	25 mg
<b>Pyridoxine Hydrochloride</b> (UNII: 68Y4CF58BV) (Pyridoxine - UNII:KV2JZ1B16Z)	Pyridoxine Hydrochloride	25 mg
<b>Folic Acid</b> (UNII: 935E97BOY8) (Folic Acid - UNII:935E97BOY8)	Folic Acid	1 mg
<b>Biotin</b> (UNII: 6SO6U10H04) (Biotin - UNII:6SO6U10H04)	Biotin	100 ug
<b>Cyanocobalamin</b> (UNII: P6YC3EG204) (Cyanocobalamin - UNII:P6YC3EG204)	Cyanocobalamin	50 ug
<b>Selenium</b> (UNII: H6241UJ22B) (Selenium - UNII:H6241UJ22B)	Selenium	100 ug
<b>Magnesium Oxide</b> (UNII: 3A3U0GI71G) (Magnesium Cation - UNII:T6V3LHY838)	Magnesium Cation	50 mg
<b>Zinc Oxide</b> (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	25 mg
<b>Cupric Sulfate</b> (UNII: LRX7AJ16DT) (Cupric Cation - UNII:8CBV67279L)	Cupric Cation	1.5 mg
<b>Manganese</b> (UNII: 42Z2K6ZL8P) (Manganese - UNII:42Z2K6ZL8P)	Manganese	1.5 mg
<b>Chromium</b> (UNII: 0R0008Q3JB) (Chromium - UNII:0R0008Q3JB)	Chromium	50 ug
<b>THIOCTIC ACID</b> (UNII: 73Y7P0K73Y) (THIOCTIC ACID - UNII:73Y7P0K73Y)	THIOCTIC ACID	15 mg
<b>Lutein</b> (UNII: X72A60C9MT) (Lutein - UNII:X72A60C9MT)	Lutein	5 mg

**Inactive Ingredients**

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

MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)

.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01)

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	EV0207
<b>Contains</b>			

### 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	
2		3 in 1 BLISTER PACK; Type 0: Not a Combination Product		

### 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: 4/2018

Exeltis USA, Inc.