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 overdosage. 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 hyper-calcemia 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.

KEEP OUT OF REACH OF CHILDREN.

Rx

MANUFACTURED IN THE USA

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

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

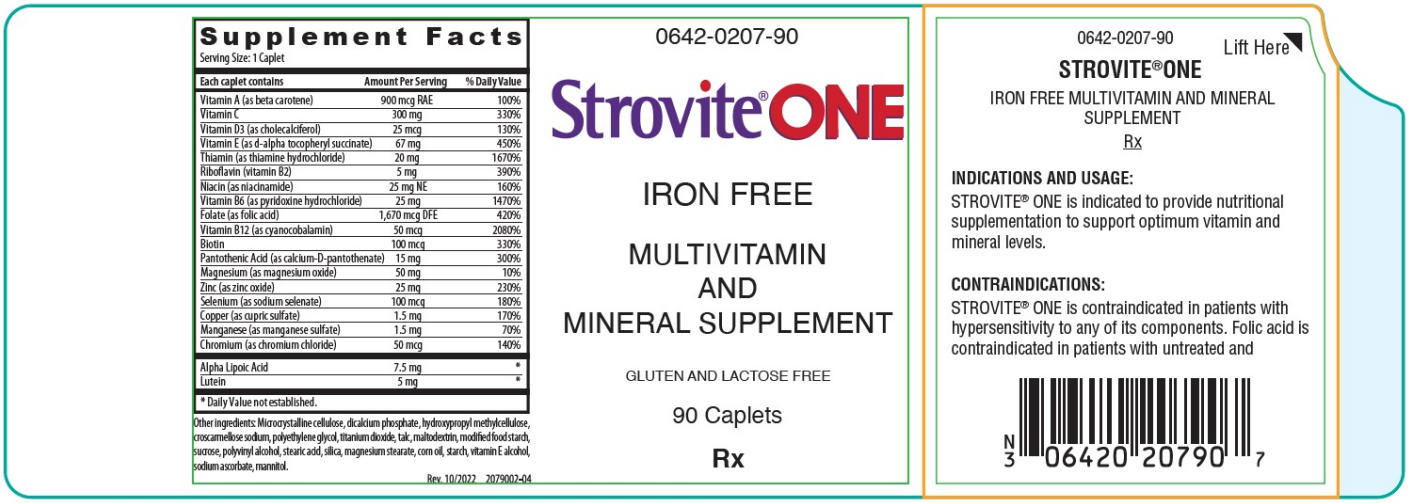
AND

MINERAL SUPPLEMENT

GLUTEN AND LACTOSE FREE

90 Caplets

Rx



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:2M83C4R6ZB)	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: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	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: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	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
HYDROXYPROPYL METHYLCELLULOSE (UNII: 3NXW29V3WO)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MANNITOL (UNII: 3OWL53L36A)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
SUCROSE (UNII: C151H8M554)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
TOCOPHEROL (UNII: R0ZB2556P8)	
SODIUM ASCORBATE (UNII: S033EH8359)	
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01)	
MODIFIED CORN STARCH (1-OCTENYL SUCCINIC ANHYDRIDE) (UNII: 461P5CJN6T)	
CORN OIL (UNII: 8470G57WFM)	

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	
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: 3/2025 Exeltis USA, Inc.