

ELITE OB PRENATAL MULTIVITAMIN- beta carotene, thiamine mononitrate, riboflavin, pyridoxine hcl, cyanocobalamin, folic acid, cholecalciferol, ascorbic acid, d-alpha succinate, niacinamide, pantothenic acid, gluconate, magnesium oxide, zinc oxide and ferronyl, micronised tablet
Trigen Laboratories, LLC

Elite OB™

SUPPLEMENT FACTS

Supplement Facts

Serving Size: 1 Caplet

Servings Per Container: 100

	Amount Per Serving	% DV for Pregnant and Lactating Women
Vitamin A (as Beta Carotene)	630 mcg RAE (2100 IU)	48%
Vitamin C (Ascorbic Acid)	120 mg	100%
Vitamin D (as Cholecalciferol)	8 mcg (315 IU)	53%
Vitamin E (as d-Alpha Tocopheryl Succinate)	13 mg* (20 IU)	68%
Thiamin (as Thiamine Mononitrate)	2 mg	143%
Riboflavin	3.4 mg	213%
Niacin (as Niacinamide)	10 mg NE	56%
Vitamin B ₆ (as Pyridoxine HCl)	10 mg	500%
Folate	2083 mcg DFE (1250 mcg Folic Acid)	347%
Vitamin B ₁₂ (as Cyanocobalamin)	15 mcg	536%
Pantothenic Acid	5 mg	71%
Iron (Ferronyl [®] Carbonyl)	50 mg	185%
Magnesium (as Magnesium Oxide)	15 mg	4%
Zinc (as Zinc Oxide)	10 mg	77%
Copper (as Copper Gluconate)	1 mg	77%
*Equal to mg alpha-tocopherol		

Other Ingredients: Microcrystalline Cellulose, Di Cal Phosphate, Croscarmellose Sodium, Pink Color Coating (Hydroxypropylmethyl Cellulose, Polyvinyl Alcohol, Titanium Dioxide, Polyethylene Glycol, Talc, FD&C Red #40 Lake), Fumed Silica, Stearic Acid, Magnesium Stearate, Povidone K30, Acacia.

GLUTEN, SUGAR, AND LACTOSE FREE

Elite OB™ is a prescription multivitamin/multimineral indicated for use in improving the nutritional status of women prior to conception, throughout pregnancy, and in the postnatal period for both lactating and non-lactating mothers.

CONTRAINDICATIONS

Elite OB™ should not be used by patients with a known hypersensitivity to any of the listed ingredients.

WARNINGS

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. KEEP THIS PRODUCT OUT OF THE REACH OF CHILDREN. In case of accidental overdose, call a doctor or poison control center immediately.

PRECAUTIONS

Folic acid alone is an improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B₁₂ is deficient. Folic acid in doses above 0.1 mg daily may obscure pernicious anemia, in that hematologic remission can occur while neurological manifestations remain progressive. Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

The patient's medical conditions and consumption of other drugs, herbs, and/or supplements should be considered.

DRUG INTERACTIONS

Elite OB™ caplets are not recommended for and should not be given to patients receiving levodopa because the action of levodopa is antagonized by pyridoxine. There is a possibility of increased bleeding due to pyridoxine interaction with anticoagulants (e.g., Aspirin, Heparin, Clopidogrel).

ADVERSE REACTIONS

Adverse reactions have been reported with specific vitamins and minerals but generally at levels substantially higher than those contained herein. However, allergic and idiosyncratic reactions are possible at lower levels. Iron, even at the usual recommended levels, has been associated with gastrointestinal intolerance in some patients.

DESCRIPTION

Elite OB™ is a pink capsule shaped caplet imprinted with "VP 010".

DIRECTIONS FOR USE

Take one caplet by mouth daily or as directed by a physician.

HOW SUPPLIED

Elite OB™ is available as a pink capsule shaped caplet. Available in unit-dose pack of 100 (10x10)

STORAGE

Store at controlled room temperature 15°-30°C (59°-86°F). [See USP]. Protect from light and moisture and avoid excessive heat.

KEEP OUT OF REACH OF CHILDREN.

For use on the order of a healthcare practitioner.

Call your doctor about side effects. To report side effects, call Trigen Laboratories, LLC at 1-770-509-4500 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

PLR-EOB-00002-1 Rev. 12/2021

Manufactured for:

Trigen Laboratories, LLC

Alpharetta, GA 30005

www.trigenlab.com



PRINCIPAL DISPLAY PANEL - 100 tablet label

13811-027-10

Elite OB™

**Prenatal
Multivitamin**

**TRIGEN
LABORATORIES**

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:13811-027
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VITAMIN A (UNII: 81G40H8B0T) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	2100 [iU]
THIAMINE (UNII: X66NSO3N35) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	2 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	3.40 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	10 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	15 ug
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1.25 mg
VITAMIN D (UNII: 9VU1KI44GP) (CHOLECALCIFEROL - UNII:1C6V77QF41)	VITAMIN D	315 [iU]
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	120 mg
.ALPHA.-TOCOPHEROL SUCCINATE, D- (UNII: LU4B53JYVE) (.ALPHA.-TOCOPHEROL, D- - UNII:N9PR3490H9)	.ALPHA.-TOCOPHEROL SUCCINATE, D-	20 [iU]
NIACINAMIDE (UNII: 25X5118RD4) (NIACINAMIDE - UNII:25X5118RD4)	NIACINAMIDE	10 mg
PANTOTHENIC ACID (UNII: 19F5HK2737) (PANTOTHENIC ACID - UNII:19F5HK2737)	PANTOTHENIC ACID	5 mg
COPPER (UNII: 789U1901C5) (COPPER - UNII:789U1901C5)	COPPER	1 mg
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM OXIDE	15 mg
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	10 mg
Iron (UNII: E1UOL152H7) (Iron - UNII:E1UOL152H7)	Iron	50 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE K30 (UNII: U725QWY32X)	
ACACIA (UNII: 5C5403N26O)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
ETHYLCELLULOSES (UNII: 7Z8S9VYZ4B)	
TALC (UNII: 7SEV7J4R1U)	
MINERAL OIL (UNII: T5L8T28FGP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:13811-027-10	10 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		07/13/2013	

Supplement Facts**Serving Size :****Serving per Container :**

	Amount Per Serving	% Daily Value
color		
imprint		
scoring	1	
shape		
size (solid drugs)	19 mm	

Labeler - Trigen Laboratories, LLC (830479668)

Revised: 12/2021

Trigen Laboratories, LLC