

CORVITA- .beta.-carotene, ascorbic acid, cholecalciferol, .alpha.-tocopherol succinate, d-, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, biotin, pantothenic acid, iron, magnesium oxide, zinc oxide, selenomethionine, copper gluconate, chromium picolinate, thiocctic acid, lutein, and lycopene tablet, coated
Trigen Laboratories, LLC

CORVITA™
Multivitamin & Mineral
Supplement with Iron

SUPPLEMENT FACTS

Supplement Facts

Serving Size: 1 Tablet
Servings Per Container: 100

	Amount Per Serving	% DV Adults & Children 4 Years or More
Calories	0	
Total Carbohydrate	Less than 1 g	<1%†
Vitamin A (as Beta Carotene)	225 mcg RAE (750 IU)	25%
Vitamin C (Ascorbic Acid)	375 mg	417%
Vitamin D (as Cholecalciferol)	8 mcg (315 IU)	40%
Vitamin E (as d-Alpha Tocopheryl Succinate)	84 mg** (125 IU)	560%
Thiamin (as Thiamine Mononitrate)	25 mg	2083%
Riboflavin	3.4 mg	262%
Niacin (as Niacinamide)	35 mg NE	219%
Vitamin B ₆ (as Pyridoxine HCl)	35 mg	2059%
Folate	2083 mcg DFE (1250 mcg Folic Acid)	521%
Vitamin B ₁₂ (as Cyanocobalamin)	70 mcg	2917%
Biotin	75 mcg	250%
Pantothenic Acid (as d-Calcium Pantothenate)	5 mg	100%
Iron (as Ferronyl® Iron, Micronized)	13 mg	72%
Magnesium (as Magnesium Oxide)	35 mg	8%
Zinc (as Zinc Oxide)	35 mg	318%
Selenium (as Sodium Selenate 2%)	125 mcg	227%
Copper (as Copper Gluconate)	1 mg	111%
Chromium (as Chromium Picolinate)	150 mcg	429%
Alpha Lipoic Acid	10 mg	*
Lutein	350 mcg	*
Lycopene	125 mcg	*

†Percent Daily Values are based on a 2,000 calorie diet
*Daily Value (DV) not established
**Equal to mg alpha-tocopherol

Other Ingredients: Silicified Microcrystalline Cellulose, Microcrystalline Cellulose, Green Color Coating (Hydroxypropylmethyl Cellulose, Titanium Dioxide, Polyvinyl Alcohol, Triacetin, Talc, FD&C Yellow #5 Lake, FD&C Blue #2 Lake, FD&C Yellow #6 Lake), Croscarmellose Sodium, Fumed Silica, Tri- Potassium Citrate, Magnesium Stearate, Stearic Acid, and Citric Acid.

Sugar, Lactose, and Gluten Free

CORVITA™ is a prescribed Multivitamin/Mineral Supplement with Iron that is specially formulated and indicated for the distinct nutritional requirements of individuals with vitamin deficiencies.

INDICATIONS AND USAGE

CORVITA™ Multivitamins/Minerals with Iron tablets are indicated for the distinctive nutritional requirements of persons being treated for vitamin deficiencies by a physician.

CONTRAINDICATIONS

CORVITA™ Multivitamin/Mineral Supplement with Iron tablets should not be used by patients with known history of hypersensitivity to any of the listed ingredients or as directed by your physician.

WARNING

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

Folic acid alone is 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 assessment, such that hematologic remission can occur while neurological manifestations remain progressive.

This product contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

Biotin levels higher than the recommended daily allowance may cause interference with some laboratory tests, including cardiovascular diagnostic test (e.g. troponin) and hormone tests, and may lead to incorrect test results. Tell your healthcare provider about all prescription and over-the-counter medicines, vitamins, and dietary supplements that you take, including biotin.

DRUG INTERACTIONS

CORVITA™ Multivitamin & Mineral Supplement with Iron tablets 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 in CORVITA™. 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

CORVITA™ is a green coated, oval shaped tablet debossed with “VP 011” on one side, bisect on the other side.

DIRECTIONS FOR USE

Usual adult dosage is one bisected tablet daily, or as prescribed by a physician.

HOW SUPPLIED

Corvita™ tablets are supplied in bottles of 100 tablets.

Product Code: 13811-028-10

STORAGE

Store at 20°-25°C (68°-77°F), excursion permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature]. Protect from light and moisture and avoid excessive heat. Dispense in a tight, light resistant container as defined by the USP with a child-resistant closure.

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-CORVITA-00001-02 Rev. 12/2021

Manufactured for:



Trigen Laboratories, LLC

Alpharetta, GA 30005

1-770-509-4500

PRINCIPAL DISPLAY PANEL - 100 Tablet Bottle Label

13811-028-10

CORVITA™ TABLETS

MULTIVITAMIN / MINERAL SUPPLEMENT WITH IRON

Sugar, Lactose and Gluten Free

100 TABLETS

13811-028-10

CORVITA™

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Sugar, Lactose & Gluten Free
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Lot: _____
Exp: _____

TRIGEN
LABORATORIES

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Calories	0	Biotin	75 mcg 250%
Total Carbohydrate	Less than 1 g <1%	Pantothenic Acid (as d-Calcium Pantothenate)	5 mg 100%
Vitamin A (as Beta Carotene)	225 mcg RAE (750 IU) 25%	Iron (as Ferrous [®] Iron, Microencapsulated)	13 mg 72%
Vitamin C (Ascorbic Acid)	375 mg 417%	Magnesium (as Magnesium Oxide)	35 mg 8%
Vitamin D (as Cholecalciferol)	8 mcg (315 IU) 40%	Zinc (as Zinc Oxide)	35 mg 318%
Vitamin E (as d-Alpha Tocopheryl Succinate)	84 mg** (125 IU) 568%	Selenium (as Sodium Selenate 2%)	125 mcg 227%
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Niacin (as Niacinamide)	35 mg NE 219%	Alpha Lipoic Acid	10 mg *
Vitamin B ₆ (as Pyridoxine HCl)	35 mg 2059%	Lutein	350 mcg *
Folate	2083 mcg DFE 521%	Lycopene	125 mcg *
	(1250 mcg Folic Acid)		
Vitamin B ₁₂ (as Cyanocobalamin)	70 mcg 2917%		

*Percent Daily Values are based on a 2,000 calorie diet
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** Equal to mcg alpha-tocopherol

Other Ingredients: Silicified Microcrystalline Cellulose, Microcrystalline Cellulose, Green Color Coating (Hydroxypropylmethyl Cellulose, Titanium Dioxide, Polyvinyl Alcohol, Triacetin, Talc, FD&C Yellow #5 Lake, FD&C Blue #2 Lake, FD&C Yellow #6 Lake), Croscarmellose Sodium, Fumed Silica, Tri-Potassium Citrate, Magnesium Stearate, Stearic Acid, and Citric Acid.
Sugar, Lactose, and Gluten Free
Manufactured for: Trigen Laboratories, LLC Alpharetta, GA 30005
www.trigenlab.com PLR-CORVITA-00001-02 Rev. 12/2021

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Peel label for prescribing and production information.

CORVITA

.beta.-carotene, ascorbic acid, cholecalciferol, .alpha.-tocopherol succinate, d-, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, biotin, pantothenic acid, iron, magnesium oxide, zinc oxide, selenomethionine, copper gluconate, chromium picolinate, thioctic acid, lutein, and lycopene tablet, coated

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:13811-028
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BETA CAROTENE (UNII: 01YAE03M7J) (BETA CAROTENE - UNII:01YAE03M7J)	BETA CAROTENE	750 [iU]

.ALPHA.-TOCOPHEROL SUCCINATE, D- (UNII: LU4B53JYVE) (.ALPHA.-TOCOPHEROL, D- - UNII:N9PR3490H9)	.ALPHA.-TOCOPHEROL SUCCINATE, D-	125 [iU]
cholecalciferol (UNII: 1C6V77QF41) (cholecalciferol - UNII:1C6V77QF41)	cholecalciferol	315 [iU]
ascorbic acid (UNII: PQ6CK8PD0R) (ascorbic acid - UNII:PQ6CK8PD0R)	ascorbic acid	375 mg
thiamine mononitrate (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	Thiamine	25 mg
riboflavin (UNII: TLM2976OFR) (riboflavin - UNII:TLM2976OFR)	riboflavin	3.4 mg
niacinamide (UNII: 25X51I8RD4) (niacinamide - UNII:25X51I8RD4)	niacinamide	35 mg
folic acid (UNII: 935E97BOY8) (folic acid - UNII:935E97BOY8)	folic acid	1.25 mg
pyridoxine Hydrochloride (UNII: 68Y4CF58BV) (pyridoxine - UNII:KV2JZ1BI6Z)	pyridoxine Hydrochloride	35 mg
Biotin (UNII: 6SO6U10H04) (Biotin - UNII:6SO6U10H04)	Biotin	75 ug
Pantothenic Acid (UNII: 19F5HK2737) (Pantothenic Acid - UNII:19F5HK2737)	Pantothenic Acid	5 mg
cyanocobalamin (UNII: P6YC3EG204) (cyanocobalamin - UNII:P6YC3EG204)	cyanocobalamin	70 ug
Magnesium oxide (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	Magnesium oxide	35 mg
Zinc oxide (UNII: SOI2LOH54Z) (Zinc oxide - UNII:SOI2LOH54Z)	Zinc oxide	35 mg
SODIUM SELENATE (UNII: 5DQP25600A) (SELENATE ION - UNII:6X37R1DB70)	SELENIUM	125 ug
Chromium picolinate (UNII: S71T8B8Z6P) (CHROMIC CATION - UNII:X1N4508KF1)	CHROMIC CATION	150 ug
Copper gluconate (UNII: RV823G6G67) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	1 mg
IRON (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)	IRON	13 mg
Lutein (UNII: X72A60C9MT) (Lutein - UNII:X72A60C9MT)	Lutein	350 ug
Lycopene (UNII: SB0N2N0WW6) (Lycopene - UNII:SB0N2N0WW6)	Lycopene	125 ug
THIOCTIC ACID (UNII: 73Y7P0K73Y) (THIOCTIC ACID - UNII:73Y7P0K73Y)	THIOCTIC ACID	10 mg

Inactive Ingredients

Ingredient Name	Strength
Cellulose, Microcrystalline (UNII: OP1R32D61U)	
croscarmellose sodium (UNII: M28OL1HH48)	
titanium dioxide (UNII: 15FIX9V2JP)	
potassium citrate anhydrous (UNII: 86R1NVR0HW)	
stearic acid (UNII: 4ELV7Z65AP)	
magnesium stearate (UNII: 70097M6I30)	
citric acid monohydrate (UNII: 2968PHW8QP)	
talc (UNII: 7SEV7J4R1U)	
FD&C Yellow No. 5 (UNII: I753WB2F1M)	
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
FD&C BLUE NO. 2--ALUMINUM LAKE (UNII: 4AQJ3LG584)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
TRIACETIN (UNII: XHX3C3X673)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:13811-028-10	100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		03/01/2011	

Supplement Facts		
Serving Size :	Serving per Container :	
	Amount Per Serving	% Daily Value
color		
imprint		
scoring	2	
shape		
size (solid drugs)	19 mm	

Labeler - Trigen Laboratories, LLC (830479668)

Revised: 12/2021

Trigen Laboratories, LLC