

**COMPLETENATE CHEWABLE- .beta.-carotene, ascorbic acid, sodium ascorbate, cholecalciferol, .alpha.-tocopherol acetate, dl-, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, and ferrous fumarate tablet  
Trigen Laboratories, LLC**

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**CompleteNate Chewable  
Chewable Prenatal Multivitamin Tablet with Iron**

**SUPPLEMENT FACTS**

# Supplement Facts

Serving Size: 1 Tablet

Servings Per Container: 90

	Amount Per Serving	% DV for Pregnant and Lactating Women
Calories	5	
Total Carbohydrate	1 g	<1% <sup>†</sup>
Total Sugar	Less than 1 g	†
Vitamin A (as Beta-Carotene)	300 mcg RAE (1000 IU)	23%
Vitamin C (as Sodium Ascorbate and Ascorbic Acid)	120 mg	100%
Vitamin D (as Cholecalciferol)	10 mcg (400 IU)	67%
Vitamin E (as dl-Alpha Tocopheryl Acetate)	5 mg* (11 IU)	26%
Thiamin (as Thiamine Mononitrate)	2 mg	143%
Riboflavin	3 mg	188%
Niacin (as Niacinamide)	20 mg NE	111%
Vitamin B <sub>6</sub> (as Pyridoxine HCl)	10 mg	500%
Folate	1667 mcg DFE (1000 mcg Folic Acid)	278%
Vitamin B <sub>12</sub> (as Cyanocobalamin)	12 mcg	429%
Iron (as Ferrous Fumarate)	29 mg	107%
*Equal to mg Alpha-Tocopherol		
†Percent Daily Values (DV) are based on a 2,000 calorie diet		

**Other Ingredients:** Sorbitol, Sucrose, Natural Orange Flavor, Orange Juice Powder, Magnesium Stearate, Stearic Acid, Gelatin, Stevia, Fumed Silica.

CompleteNate Chewable tablets are formulated to provide vitamin and mineral

supplementation throughout pregnancy and during postnatal period, for both the lactating and non-lactating mother. It is also useful for improving nutritional status prior to conception.

## **CONTRAINDICATIONS**

CompleteNate Chewable should not be used by patients with a known hypersensitivity to any of the listed ingredients. All iron compounds are contraindicated in patients with hemochromatosis, hemosiderosis, or hemolytic anemias.

**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 B<sub>12</sub> 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.

**Pediatric Use:** Safety and effectiveness in pediatric patients have not been established.

**Geriatric Use:** Safety and effectiveness in elderly patients have not been established.

## **DRUG INTERACTIONS**

CompleteNate Chewable Tablets is 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**

**Folic Acid:** Allergic sensitizations have been reported following both oral and parenteral administration of folic acid.

**Ferrous Fumarate:** Gastrointestinal disturbances (anorexia, nausea, diarrhea, constipation) occur occasionally, but are usually mild and may subside with continuation of therapy and physician encouragement. Although the absorption of iron is best when taken between meals, occasional G.I. disturbances may be controlled by giving CompleteNate Chewable shortly after meals.

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

## **OVERDOSAGE**

Iron is toxic. When overdoses are ingested by children, severe reactions, including fatalities, have resulted. CompleteNate Chewable should be stored beyond the reach of children to protect against accidental iron poisoning.

## **DESCRIPTION**

CompleteNate Chewable is an orange-flavored, round, speckled light brown tablet debossed with "TL014" on one side.

## **DIRECTIONS FOR USE**

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

## **HOW SUPPLIED**

CompleteNate Chewable is supplied in bottles of 90 tablets.

**PRODUCT CODE 13811-014-90**

## **STORAGE**

Store at 20°-25°C (68°-77°F), relative humidity no higher than 65%; excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature]. Protect from moisture and excessive heat. Note that contact with moisture may produce surface discoloration of the tablet. Dispense in a tight, light-resistant container with a child resistant closure as defined by the USP.

**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](http://www.fda.gov/medwatch).**

**PLR-CNC-00002-1**

**Rev. 12/2021**

**Manufactured for:**

**Trigen Laboratories, LLC**

Alpharetta, GA 30005

www.trigenlab.com



## PRINCIPAL DISPLAY PANEL - 90 Tablet Bottle Label

13811-014-90

90 Tablets

CompleteNate  
Chewable

Chewable Prenatal Multivitamin Tablet with Iron

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LABORATORIES

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Alpharetta, GA 30005  
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PLR.CNC.00002-1 Rev. 12/2021

13811-014-90

**CompleteNate**  
**Chewable**

Chewable Prenatal Multivitamin Tablet with Iron

90 Tablets

TRIGEN  
LABORATORIES

**DESCRIPTION**  
CompleteNate Chewable is an orange-flavored, round, speckled light brown tablet debossed with "TLO14" on one side.

**Supplement Facts**  
Serving Size: 1 Tablet  
Servings Per Container: 90

	Amount Per Serving	%DV for Pregnant and Lactating Women
Calories	5	
Total Sugar	Less than 1 g	†
Total Carbohydrate	1 g	<1%†
Vitamin A (as Beta-Carotene)	300 mcg RAE (1000 IU)	23%
Vitamin C (as Sodium Ascorbate and Ascorbic Acid)	120 mg	100%
Vitamin D (as Cholecalciferol)	10 mcg (400 IU)	67%
Vitamin E (as dl-Alpha Tocopheryl Acetate)	5 mg (11 IU)	26%
Thiamin (as Thiamine Mononitrate)	2 mg	143%
Riboflavin	3 mg	188%
Niacin (as Niacinamide)	20 mg NE	111%
Vitamin B6 (as Pyridoxine HCl)	10 mg	500%
Folate	1667 mcg DFE (1000 mcg Folic Acid)	278%
Vitamin B12 (as Cyanocobalamin)	12 mcg	429%
Iron (as Ferrous Fumarate)	29 mg	107%

† Equal to mg Alpha-tocopherol  
† Percent Daily Values (DV) are based on a 2,000 calorie diet

**Other Ingredients:**  
Sorbitol, Sucrose, Natural Orange Flavor, Orange Juice Powder, Magnesium Stearate, Stearic Acid, Gelatin, Stevia, Fumed Silica.

Peel label for prescribing and product information.

## COMPLETENATE CHEWABLE

.beta.-carotene, ascorbic acid, sodium ascorbate, cholecalciferol, .alpha.-tocopherol acetate, dl-, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, and ferrous fumarate tablet

### Product Information

<b>Product Type</b>	DIETARY SUPPLEMENT	<b>Item Code (Source)</b>	NHRIC:13811-014
<b>Route of Administration</b>	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
BETA CAROTENE (UNII: 01YAE03M7J) (BETA CAROTENE - UNII:01YAE03M7J)			BETA CAROTENE	1000 [iU]
ascorbic acid (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)			ascorbic acid	48 mg
sodium ascorbate (UNII: S033EH8359) (ASCORBIC ACID - UNII:PQ6CK8PD0R)			ASCORBIC ACID	72 mg
cholecalciferol (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)			cholecalciferol	400 [iU]
.alpha.-tocopherol acetate, dl- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)			.ALPHA.-TOCOPHEROL, DL-	11 [iU]
thiamine mononitrate (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)			THIAMINE	2 mg
riboflavin (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)			riboflavin	3 mg
niacinamide (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)			niacinamide	20 mg
pyridoxine Hydrochloride (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)			pyridoxine Hydrochloride	10 mg
folic acid (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)			folic acid	1 mg
cyanocobalamin (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)			cyanocobalamin	12 ug
ferrous fumarate (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)			FERROUS CATION	29 mg
Inactive Ingredients				
Ingredient Name				Strength
sorbitol (UNII: 506T60A25R)				
sucrose (UNII: C151H8M554)				
magnesium stearate (UNII: 70097M6I30)				
stearic acid (UNII: 4ELV7Z65AP)				
gelatin (UNII: 2G86QN327L)				
stevia rebaudiuna leaf (UNII: 6TC6NN0876)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
ORANGE OIL (UNII: AKN3KSD11B)				
ORANGE (UNII: 5EVU04N5QU)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:13811-014-90	90 in 1 BOTTLE, PLASTIC		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT			07/01/2010	

Supplement Facts	
Serving Size :	Serving per Container :
Amount Per Serving	% Daily Value
color	

flavor	
imprint	
scoring	1
shape	
size (solid drugs)	12 mm

**Labeler** - Trigen Laboratories, LLC (830479668)

Revised: 12/2021

Trigen Laboratories, LLC