

**TRINATAL RX 1- acetate ion, .beta.-carotene, cholecalciferol, .alpha.-tocopherol acetate, dl-, ascorbic acid, folic acid, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, cyanocobalamin, biotin, calcium pantothenate, calcium carbonate, magnesium oxide, ferrous fumarate, cupric oxide, and zinc oxide tablet, film coated**  
**Trigen Laboratories, LLC**

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**Trinatal Rx 1**  
**Prenatal Multivitamin/Mineral Tablet**

**SUPPLEMENT FACTS**

<b>Supplement Facts</b>		
Serving Size: 1 Tablet		
Servings Per Container: 100		
	Amount Per Serving	% DV Pregnant and Lactating Woman
Vitamin A (Acetate 3600 IU & Beta Carotene 400 IU)	1200 mcg RAE	92%
Vitamin C (Ascorbic Acid)	80 mg	67%
Vitamin D (as Cholecalciferol)	10 mcg (400 IU)	67%
Vitamin E (as dl-Alpha Tocopheryl Acetate)	7 mg* (15 IU)	37%
Thiamin (as Thiamine Mononitrate)	1.5 mg	107%
Riboflavin	1.6 mg	100%
Niacin (as Niacinamide)	17 mg NE	94%
Vitamin B <sub>6</sub> (as Pyridoxine HCl)	4 mg	200%
Folate (as Folic Acid)	1667 mcg DFE (1000 mcg folic acid)	278%
Vitamin B <sub>12</sub> (as Cyanocobalamin)	2.5 mcg	89%
Biotin	30 mcg	86%
Pantothenic Acid (as Calcium Pantothenate)	7 mg	100%
Calcium (as Calcium Carbonate)	200 mg	15%
Iron (as Ferrous Fumarate)	60 mg	222%
Magnesium (as Magnesium oxide)	100 mg	25%
Zinc (as Zinc Oxide)	25 mg	192%
Copper (as Cupric Oxide)	3 mg	231%
*Equal to mg alpha-tocopherol		

**Other Ingredients:** Microcrystalline cellulose, coating (hypromellose, titanium dioxide, polyvinyl alcohol, polyethylene glycol, talc) tripotassium citrate, croscarmellose sodium, citric acid, povidone K30, acacia, stearic acid, magnesium stearate, fumed silica.

Trinatal Rx 1 tablets help assure an adequate intake of the vitamins and minerals listed. Folate supplementation may be recommended for individuals who have higher-than-normal demands for folate such as pregnant women.

## **CONTRAINDICATIONS**

Supplemental vitamins and minerals should not be prescribed for patients with hemochromatosis or Wilson's disease.

## **WARNINGS**

**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**

**General:** 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 assessment, such that hematologic remission can occur while neurological manifestations remain progressive. Pernicious anemia should be excluded before using this product since folic acid may mask the symptoms of pernicious anemia. The calcium content should be considered before prescribing for patients with history of kidney stones. Do not exceed the recommended dose.

Biotin levels higher than the recommended daily allowance may cause interference with some laboratory tests, including cardiovascular diagnostic tests (e.g. troponin) and hormone test, 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.

**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**

Trinatal Rx 1 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**

Adverse reactions with iron therapy may include constipation, diarrhea, nausea, vomiting, dark stools and abdominal pain. Adverse reactions with iron therapy are usually transient. Allergic sensitization has been reported following both oral and parenteral administration of folic acid. Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

## **DESCRIPTION**

Trinatal Rx 1 is an oval shaped, white film-coated tablet debossed "TL388".

## **DIRECTIONS FOR USE**

Take One (1) tablet daily or as prescribed by a physician.

## **HOW SUPPLIED**

Trinatal Rx 1 is supplied in bottles of 100 tablets.

**Product Code: 13811-007-10**

## **STORAGE**

Store at 20°-25°C (68°-77°F), excursion permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature]. Dispense in a tight, light resistant container as defined in 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 at 1-800-444-5164 or FDA at 1-800-FDA-1088.**

**PI-TRX-00001-2**

**Rev. 05/2023**

**Manufactured for:**

**Trigen Laboratories, LLC**

**Alpharetta, GA 30005**



**PRINCIPAL DISPLAY PANEL - 100 Tablet Bottle Label**

**13811-007-10**

**100 Tablets**

**Trinatal Rx 1**

(one tablet daily)

## Prenatal Multivitamin/Multimineral Tablet

**TRIGEN  
LABORATORIES**

**DIRECTIONS FOR USE**  
Take One (1) tablet daily or as prescribed by a physician. See attached package insert for additional information.  
**STORAGE:** Store at 20°-25°C (68°-77°F), excursion permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature]. Dispense in a tight, light resistant container as defined in the USP with a child-resistant closure.

**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.

Call your doctor about side effects. To report side effects, call Trigen Laboratories at 1-800-444-5164 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).  
**KEEP OUT OF REACH OF CHILDREN.**  
Manufactured for:  
Trigen Laboratories, LLC  
Alpharetta, GA 30005  
[www.trigenlab.com](http://www.trigenlab.com)

BTL-TRX-00001-1 Rev. 01/2023

Lot: \_\_\_\_\_  
Exp: \_\_\_\_\_

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13811-007-10

**Trinatal Rx 1**  
(one tablet daily)

Prenatal Multivitamin/Multimineral Tablet

100 Tablets

**TRIGEN**  
LABORATORIES

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## TRINATAL RX 1

acetate ion, .beta.-carotene, cholecalciferol, .alpha.-tocopherol acetate, dl-, ascorbic acid, folic acid, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, cyanocobalamin, biotin, calcium pantothenate, calcium carbonate, magnesium oxide, ferrous fumarate, cupric oxide, and zinc oxide tablet, film coated

### Product Information

<b>Product Type</b>	DIETARY SUPPLEMENT	<b>Item Code (Source)</b>	NHRIC:13811-007
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>acetate ion</b> (UNII: 569DQM74SC) (acetate ion - UNII:569DQM74SC)	acetate ion	3600 [iU]
<b>BETA CAROTENE</b> (UNII: 01YAE03M7J) (BETA CAROTENE - UNII:01YAE03M7J)	BETA CAROTENE	400 [iU]
<b>cholecalciferol</b> (UNII: 1C6V77QF41) (cholecalciferol - UNII:1C6V77QF41)	cholecalciferol	400 [iU]
<b>.alpha.-tocopherol acetate, dl-</b> (UNII: WR1WP17EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.- TOCOPHEROL, DL-	15 [iU]
<b>ascorbic acid</b> (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ascorbic acid	80 mg
<b>folic acid</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	folic acid	1 mg
<b>thiamine mononitrate</b> (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABTOJ945J)	THIAMINE	1.5 mg
<b>riboflavin</b> (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	riboflavin	1.6 mg

<b>niacinamide</b> (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	niacinamide	17 mg
<b>pyridoxine Hydrochloride</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	pyridoxine Hydrochloride	4 mg
<b>cyanocobalamin</b> (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	cyanocobalamin	2.5 ug
<b>biotin</b> (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	biotin	30 ug
<b>calcium pantothenate</b> (UNII: 568ET80C3D) (PANTOTHENIC ACID - UNII:19F5HK2737)	PANTOTHENIC ACID	7 mg
<b>calcium carbonate</b> (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	calcium carbonate	200 mg
<b>magnesium oxide</b> (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	magnesium oxide	100 mg
<b>ferrous fumarate</b> (UNII: R5L488RYOQ) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	60 mg
<b>cupric oxide</b> (UNII: V1XJQ704R4) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	3 mg
<b>zinc oxide</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	zinc oxide	25 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>cellulose, microcrystalline</b> (UNII: OP1R32D61U)	
<b>hypromelloses</b> (UNII: 3NXW29V3WO)	
<b>titanium dioxide</b> (UNII: 15FIX9V2JP)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>talc</b> (UNII: 7SEV7J4R1U)	
<b>potassium citrate anhydrous</b> (UNII: 86R1NVR0HW)	
<b>croscarmellose sodium</b> (UNII: M28OL1HH48)	
<b>citric acid monohydrate</b> (UNII: 2968PHW8QP)	
<b>povidone K30</b> (UNII: U725QWY32X)	
<b>acacia</b> (UNII: 5C5403N26O)	
<b>stearic acid</b> (UNII: 4ELV7Z65AP)	
<b>magnesium stearate</b> (UNII: 70097M6I30)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:13811-007-10	100 in 1 BOTTLE, PLASTIC		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		03/01/2009	

### Supplement Facts

<b>Serving Size :</b>	<b>Serving per Container :</b>
<b>Amount Per Serving</b>	<b>% Daily Value</b>
color	

imprint	
scoring	1
shape	
size (solid drugs)	19 mm

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

Revised: 1/2023

Trigen Laboratories, LLC