

## Trinatal Rx 1 Prescribing Information

### Supplement Facts

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

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..

#### 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 1-888-9-TRIGEN (1-888-987-4436) or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

**Customer Service: 1-888-987-4436**

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**Manufactured for:**  
Trigen Laboratories, LLC  
Bridgewater, NJ 08807

