**TRINAZ- ascorbic acid, cholecalciferol, thiamine hydrochloride, riboflavin, pyridoxal phosphate anhydrous, folic acid, methylcobalamin, calcium carbonate, ferrous gluconate, and potassium iodide tablet, film coated**
**Foxland Pharmaceuticals, Inc.**

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**Trinaz Tablets - Prenatal/Postnatal Dietary Supplement Dispensed by Prescription†**

| Supplement Facts | | |
|---|---|---|
| **Serving Size: 1 Tablet** | **Servings per container: 30** | |
| **Amount Per Serving:** | | **%DV** |
| Vitamin C (as ascorbic acid) | 125 mg | 104% |
| Vitamin D (as cholecalciferol) | 12.5 mcg (500 IU) | 83% |
| Thiamin (as thiamine HCl) | 1.4 mg | 100% |
| Riboflavin | 1.6 mg | 100% |
| Vitamin B6 (as pyridoxal-5-phosphate) | 2.5 mg | 125% |
| Folate (as folic acid) | 1,667 mcg DFE 1 mg folic acid | 278% |
| Vitamin B12 (as methylcobalamin) | 30 mcg | 1,071% |
| Calcium (from calcium carbonate) | 200 mg | 15% |
| Iron (as ferrous gluconate) | 12 mg | 44% |
| Iodine (as potassium iodide) | 150 mcg | 52% |

**OTHER INGREDIENTS:** Microcrystalline Cellulose, Powdered Cellulose, Polyvinyl Alcohol, Polyethylene Glycol, Talc, Titanium Dioxide, Silicon Dioxide, Stearic Acid, Croscarmellose Sodium, Magnesium Stearate, Carmine, FD&C Blue #1, FD&C Blue #2

## DESCRIPTION

Trinaz Tablets is a prescription dietary supplement for use throughout pregnancy, during the postnatal period for both lactating and non-lactating mothers, and throughout the childbearing years. Trinaz Tablets may be useful in improving the nutritional status of women prior to conception.

## CONTRAINDICATIONS

Trinaz Tablets are contraindicated in patients with a known hypersensitivity to any of the ingredients. Do not take this product if you are presently taking mineral oil, unless directed by a doctor.

## WARNING AND PRECAUTIONS

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

## PRECAUTION

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 in that hematologic remission can occur while neurological manifestations progress. Trinaz Tablets should only be used under the direction and supervision of a licensed medical practitioner.

## ADVERSE REACTIONS

Allergic sensitization has been reported following both oral and parenteral administration of folic acid. You may report side effects by calling Foxland Pharmaceuticals, Inc. at 1-844-430-7499 or the FDA by calling 1-800-FDA-1088.

## DOSAGE & ADMINISTRATION

Usual adult dose is 1 tablet taken orally once or twice daily or as prescribed by a licensed medical practitioner.

## HOW SUPPLIED

Trinaz Tablets are available as purple, oblong, film coated tablets imprinted with "225" and are available in 30-count bottles (69067-225-30[1]).

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[1] Foxland Pharmaceuticals does not represent these product codes to be National Drug Codes (NDC). Product codes are formatted according to standard industry practice, to meet the formatting requirement by pedigree reporting and supply-chain control including pharmacies.

## STORAGE

Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature.]

Protect from heat, light and moisture.

Tamper Evident: Do not use if seal is broken or missing.

**Distributed by:**
**Foxland Pharmaceuticals, Inc.**
**Trussville, AL 35173**

This product is not an Orange Book product.

Dispensed by Prescription[†]

MADE IN USA

Rev. 07/19

[†]This product is a prescription-folate with or without other dietary ingredients that – due to increased folate levels increased risk associated with masking of B12 deficiency (pernicious anemia) requires administration under the care of a licensed medical practitioner (61 FR 8760).

[1-3] The most appropriate way to ensure pedigree reporting consistent with these regulatory guidelines and safety monitoring is to dispense this product only by prescription. This is not an Orange Book product. This product may be administered only under a physician's supervision and all prescriptions using this product shall be pursuant to state statutes as applicable. The ingredients, indication or claims of this product are not to be construed to be drug claims.

1. Federal Register Notice of August 2, 1973 (38 FR 20750)

2. Federal Register Notice of October 17, 1980 (45 FR 69043, 69044)

3. Federal Register Notice of March 5, 1996 (61 FR 8760)

**PRINCIPAL DISPLAY PANEL - 30 Tablet Bottle Label**

69067-225-30

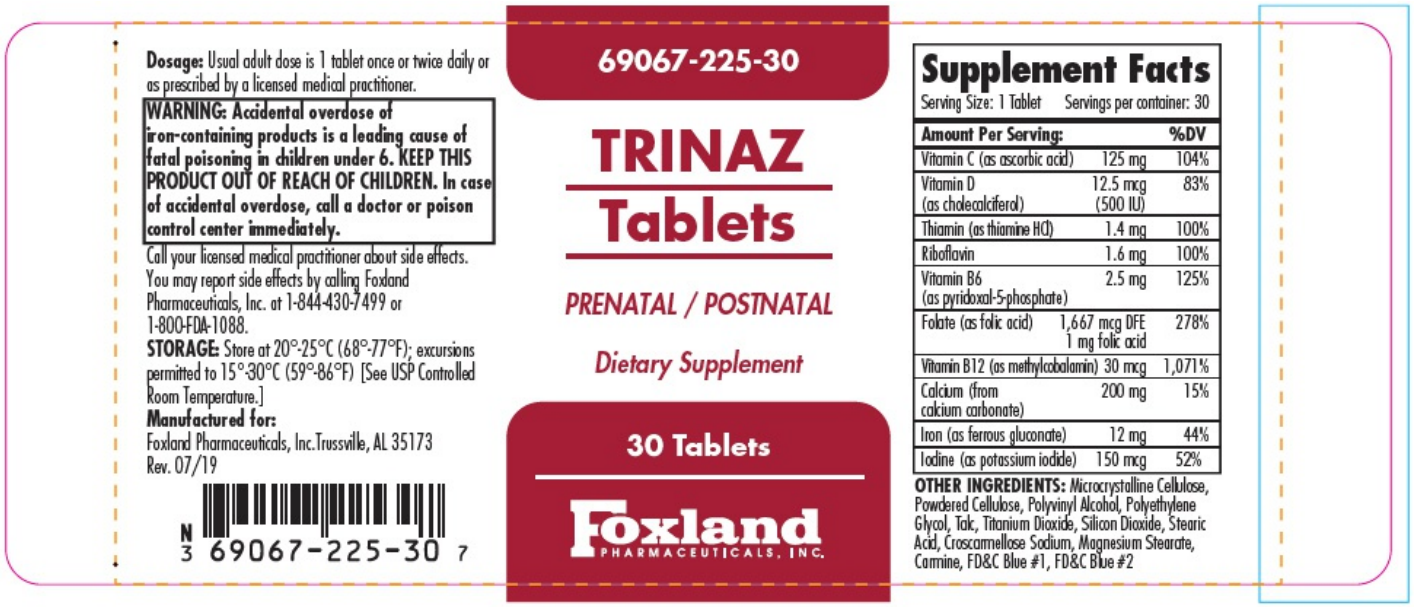
TRINAZ
Tablets

PRENATAL / POSTNATAL

Dietary Supplement

30 Tablets

Foxland
PHARMACEUTICALS, INC.




## TRINAZ

ascorbic acid, cholecalciferol, thiamine hydrochloride, riboflavin, pyridoxal phosphate anhydrous, folic acid, methylcobalamin, calcium carbonate, ferrous gluconate, and potassium iodide tablet, film coated

| Product Information | | | |
|---|---|---|---|
| **Product Type** | DIETARY SUPPLEMENT | **Item Code (Source)** | NHRIC:69067-225 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **ASCORBIC ACID** (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R) | ASCORBIC ACID | 125 mg |
| **CHOLECALCIFEROL** (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41) | CHOLECALCIFEROL | 12.5 ug |

| | | |
|---|---|---|
| **THIAMINE HYDROCHLORIDE** (UNII: M572600E5P) (THIAMINE ION - UNII:4ABT0J945J) | THIAMINE HYDROCHLORIDE | 1.4 mg |
| **RIBOFLAVIN** (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR) | RIBOFLAVIN | 1.6 mg |
| **PYRIDOXAL PHOSPHATE ANHYDROUS** (UNII: F06SGE49M6) (PYRIDOXAL PHOSPHATE ANHYDROUS - UNII:F06SGE49M6) | PYRIDOXAL PHOSPHATE ANHYDROUS | 2.5 mg |
| **FOLIC ACID** (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8) | FOLIC ACID | 1 mg |
| **METHYLCOBALAMIN** (UNII: BR1SN1JS2W) (METHYLCOBALAMIN - UNII:BR1SN1JS2W) | METHYLCOBALAMIN | 30 ug |
| **CALCIUM CARBONATE** (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB) | CALCIUM CATION | 200 mg |
| **FERROUS GLUCONATE** (UNII: U1B11I423Z) (FERROUS CATION - UNII:GW89581OWR) | FERROUS CATION | 12 mg |
| **POTASSIUM IODIDE** (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q) | IODIDE ION | 150 ug |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |
| **POWDERED CELLULOSE** (UNII: SMD1X3XO9M) | |
| **POLYVINYL ALCOHOL, UNSPECIFIED** (UNII: 532B59J990) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WJQ0SDW1A) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **CARMINIC ACID** (UNII: CID8Z8N95N) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |
| **FD&C BLUE NO. 2** (UNII: L06K8R7DQK) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NHRIC:69067-225-30 | 30 in 1 BOTTLE | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| DIETARY SUPPLEMENT | | 08/21/2019 | |

## Supplement Facts

**Serving Size :** **Serving per Container :**

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

**Labeler -** Foxland Pharmaceuticals, Inc. (079407828)

Revised: 8/2019 Foxland Pharmaceuticals, Inc.