**NATAFORT- ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, and iron tablet**
**Mission Pharmacal Company**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

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**NataFort®**
**PRENATAL MULTIVITAMIN TABLET WITH IRON**

## DESCRIPTION

NataFort® is a prescription prenatal/postnatal multivitamin/mineral supplement. The tablet is white, coated, and oval in shape, and is debossed "N1" on one side and is blank on the other.

| **Each prenatal tablet contains:** | |
|---|---|
| Vitamin C (Ascorbic acid) | 120 mg |
| Vitamin $D_3$ (Cholecalciferol) | 400 IU |
| Vitamin E (dl-alpha tocoperyl acetate) | 11 IU |
| Thiamin (Vitamin $B_1$) | 2 mg |
| Riboflavin (Vitamin $B_2$) | 3 mg |
| Niacinamide (Vitamin $B_3$) | 20 mg |
| Vitamin $B_6$ (Pyridoxine HCl) | 10 mg |
| Folic Acid | 1 mg |
| Vitamin $B_{12}$ (Cyanocobalamin) | 12 mcg |
| Iron (Ferrous fumarate, carbonyl iron) | 60 mg |

## INDICATIONS

NataFort® is a multivitamin/mineral prescription drug indicated for use in improving the nutritional status of women prior to conception, throughout pregnancy, and in the postnatal period for both lactating and nonlactating mothers.

## CONTRAINDICATIONS

This product is contraindicated in patients with a known hypersensitivity to any of the ingredients.

**WARNING**

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

## WARNING

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin $B_{12}$ is deficient.

## PRECAUTIONS

Folic acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations progress.

## ADVERSE REACTIONS

Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

## DOSAGE AND ADMINISTRATION

One tablet daily or as directed by a physician.

Store at controlled room temperature.

**NOTICE:** Contact with moisture can discolor or erode the tablet.

## HOW SUPPLIED

Bottles of 90 tablets each - **NDC** 0178-0716-90.

US Patent 6,521,247

MISSION PHARMACAL COMPANY
San Antonio, TX USA 78230 1355



L071690 C01 Rev 005110

## PRINCIPAL DISPLAY PANEL - 90 Tablet Bottle Label

**NDC** 0178-0716-90

**NataFort®**
**PRENATAL MULTIVITAMIN TABLET WITH IRON**
**For use before, during and after pregnancy**

90 Tablets

Rx Only

**Mission®**
PHARMACAL

**US Patent 6,521,247**


# NATAFORT

ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, and iron tablet

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:0178-0716 |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **Ascorbic acid** (UNII: PQ6CK8PD0R) (Ascorbic acid - UNII:PQ6CK8PD0R) | Ascorbic acid | 120 mg |
| **Cholecalciferol** (UNII: 1C6V77QF41) (Cholecalciferol - UNII:1C6V77QF41) | Cholecalciferol | 400 [iU] |
| **.alpha.-tocopherol acetate, dl-** (UNII: WR1WPI7EW8) (.alpha.-tocopherol acetate, dl- - UNII:WR1WPI7EW8) | .alpha.-tocopherol acetate, dl- | 11 [iU] |
| **Thiamine mononitrate** (UNII: 8K0I04919X) (Thiamine - UNII:X66NSO3N35) | Thiamine mononitrate | 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 |
| **Iron** (UNII: E1UOL152H7) (Iron - UNII:E1UOL152H7) | Iron | 60 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **polyethylene glycols** (UNII: 3WJQ0SDW1A) | |
| **calcium carbonate** (UNII: H0G9379FGK) | |
| **povidone** (UNII: FZ989GH94E) | |
| **cellulose, microcrystalline** (UNII: OP1R32D61U) | |
| **croscarmellose sodium** (UNII: M28OL1HH48) | |
| **titanium dioxide** (UNII: 15FIX9V2JP) | |
| **magnesium silicate** (UNII: 9B9691B2N9) | |

| | |
|---|---|
| **vitamin a palmitate** (UNII: 1D1K0N0VVC) | |
| **magnesium stearate** (UNII: 70097M6I30) | |
| **ethyl vanillin** (UNII: YC9ST449YJ) | |
| **Dimethylaminoethyl methacrylate - butyl methacrylate - methyl methacrylate copolymer** (UNII: 905HNO1SIH) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | WHITE | **Score** | no score |
| **Shape** | OVAL | **Size** | 14mm |
| **Flavor** | | **Imprint Code** | N1 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:0178-0716-90 | 90 in 1 BOTTLE | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| Unapproved drug other | | 08/25/2011 | |

## Labeler - Mission Pharmacal Company (008117095)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Mission Pharmacal Company | | 927726893 | MANUFACTURE |

Revised: 8/2011 Mission Pharmacal Company