

CITRANATAL DHA- vitamin c, calcium, iron, vitamin d3, vitamin e, thiamin, riboflavin, niacinamide, vitamin b6, folic acid, iodine, zinc, copper, docusate sodium 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.

CitraNatal® DHA

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.

DESCRIPTION

CitraNatal® DHA is a prescription prenatal/postnatal multivitamin/mineral tablet with Ferr-Ease®, a patented dual-iron delivery comprising both a quick release and slow release iron, and a capsule of an essential fatty acid. The prenatal vitamin is a white, scored, oval multivitamin/mineral tablet. The tablet is debossed “CN RX” on one side and is blank on the other. The essential fatty acid DHA capsule is caramel colored and contains a light yellow to orange semi-solid mixture.

Each prenatal tablet contains :

Vitamin C (Ascorbic acid)	120 mg
Calcium (Calcium citrate)	125 mg
Iron (Carbonyl iron, ferrous gluconate)	27 mg
Vitamin D3 (Cholecalciferol)	400 IU
Vitamin E (dl-alpha tocopheryl acetate)	30 IU
Thiamin (Vitamin B1)	3 mg
Riboflavin (Vitamin B2)	3.4 mg
Niacinamide (Vitamin B3)	20 mg
Vitamin B6 (Pyridoxine)	20 mg
Folic Acid	1 mg
Iodine (Potassium iodide)	150 mcg
Zinc (Zinc oxide)	25 mg
Copper (Cupric oxide)	2 mg
Docusate Sodium	50 mg

Each DHA gelatin capsule contains :

Docosahexaenoic Acid ((DHA, 40% from 625 mg Algal Oil) 250 mg Eicosapentaenoic Acid (EPA)..... Not more than 0.625 mg Other ingredients in DHA gelatin capsule: High Oleic Sunflower Oil, Sunflower Lecithin, Rosemary Extract, Tocopherols, Ascorbyl Palmitate.

INDICATIONS

[Insert Clinical Pharmacology General text here]

CONTRAINDICATIONS

[Insert Mechanism of Action text here]

WARNING

Ingestion of more than 3 grams of omega-3 fatty acids per day has been shown to have potential antithrombotic effects, including an increased bleeding time and INR. Administration of omega-3 fatty acids should be avoided in patients on anticoagulants and in those known to have an inherited or acquired bleeding diathesis.

WARNING: Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B12 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 and one capsule daily or as directed by a physician.

STORAGE

Store at 20-25°C (68-77°F)

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

HOW SUPPLIED

Six child-resistant blister packs of 5 tablets and 5 capsules each - **NDC 0178-0898-30**

To report a serious adverse event or obtain product information, call (210) 696-8400.

500238

C01 Rev 011110

DHA capsules manufactured for:
MISSION PHARMACAL COMPANY
San Antonio, TX USA 78230 1355

Prenatal tablets manufactured by:
MISSION PHARMACAL COMPANY
San Antonio, TX USA 78230 1355

CitraNatal® DHA Carton
NDC: 0178-0898-30



CITRANATAL DHA

vitamin c, calcium, iron, vitamin d3, vitamin e, thiamin, riboflavin, niacinamide, vitamin b6, folic acid, iodine, zinc, copper, docusate sodium tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0178-0898
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
CALCIUM CITRATE (UNII: MLM29U2X85) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CITRATE	125 mg
IRON (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)	IRON	27 mg
VITAMIN D (UNII: 9VU1K144GP) (CHOLECALCIFEROL - UNII:1C6V77QF41)	VITAMIN D	400 [iU]
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) (.ALPHA.-TOCOPHEROL - UNII:H4N855PNZ1)	.ALPHA.-TOCOPHEROL	30 [iU]
THIAMINE (UNII: X66NSO3N35) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	3 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	3.4 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	20 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	20 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
POTASSIUM IODIDE (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	POTASSIUM IODIDE	150 mg
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	25 mg
CUPRIC OXIDE (UNII: V1XJQ704R4) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	2 mg
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg

Inactive Ingredients

Ingredient Name	Strength
POVIDONES (UNII: FZ989GH94E)	132.2 mg
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	30.6 mg
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	30.5 mg
NIACINAMIDE (UNII: 25X51I8RD4)	25 mg
MAGNESIUM SILICATE (UNII: 9B9691B2N9)	5.1 mg
THIAMINE MONONITRATE (UNII: 8K0I04919X)	3.9 mg
SHELLAC (UNII: 46N107B71O)	2.6 mg
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	2 mg
ETHYL VANILLIN (UNII: YC9ST449YJ)	.7 mg
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	.15 mg
VITAMIN D (UNII: 9VU1K144GP)	.02 mg

Product Characteristics

Color	BROWN (caramel)	Score	2 pieces
Shape	CAPSULE	Size	10mm
Flavor		Imprint Code	CN;RX
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0178-0898-30	6 in 1 CARTON		
1		5 in 1 BLISTER PACK		
1		5 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		11/20/2007	

Labeler - Mission Pharmacal Company (008117095)

Registrant - Mission Pharmacal Company (927726893)

Establishment

Name	Address	ID/FEI	Business Operations
Mission Pharmacal Company		927726893	MANUFACTURE(0178-0898)

Establishment

Name	Address	ID/FEI	Business Operations
Robinson Pharma, Inc.		831560578	MANUFACTURE(0178-0898)

Establishment

Name	Address	ID/FEI	Business Operations
Accucaps Industries Limited		248441727	MANUFACTURE(0178-0898)

Revised: 3/2013

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