

CITRANATAL BLOOM DHA- iron, folic acid, cyanocobalamin, ascorbic acid, docusate sodium and dha

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 Bloom DHA

Rx Prenatal Vitamin Tablet and 300 mg DHA Capsule

CitraNatal Bloom™ DHA is a prescription prenatal/postnatal multi-vitamin/mineral tablet with Ferr-Ease®, a patented dual-iron delivery comprising both a quick release and slow release iron, and a soft gel of DHA, an essential fatty acid. The prenatal vitamin is a green, modified rectangle shaped, film-coated tablet, debossed with “CB” on one side and blank on the other. The essential fatty acid DHA soft gel is oblong, light brown and contains a yellow to orange fill.

Each prenatal tablet contains:

- Iron (Carbonyl iron, ferrous gluconate).....90 mg
- Folic Acid1 mg
- Vitamin B12 (Cyanocobalamin)12 mcg
- Vitamin C (Ascorbic acid).....120 mg
- Docusate sodium50 mg

Povidone, croscarmellose sodium, acrylic resin, color added, FD&C Yellow No. 5, magnesium stearate, magnesium silicate, FD&C Blue No. 1, polyethylene glycol, vitamin A palmitate, ethyl vanillin.

CitraNatal Bloom DHA is a multi-vitamin/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.

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: 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.

CAUTION: Exercise caution to ensure that the prescribed dosage of DHA does not exceed 1 gram (1000 mg) per day.

Please consult your health care provider with any dietary concerns.

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

One tablet and one soft gel daily or as directed by a physician.

STORAGE: Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F). Brief exposure to temperatures up to 40°C (104°F) may be

tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized.

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

Six child-resistant blister packs of 5 tablets and 5 soft gels each – NDC 0178-00816-30.

To report a serious adverse event or obtain product information, call (800) 298-1087.

MISSION PHARMACAL COMPANY, San Antonio, TX 78230 1355

51080R0717

MISSION[®] PHARMACAL

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

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Ferr-Ease[®]

Dual-iron delivery

Trademark of Mission Pharmacal Company

U.S. Patent No. 6,521,247

life's DHA[®]

life'sDHA is a trademark of DSM.

U.S. Patent No. 7,579,174

U.S. Patent No. 7,732,170

U.S. Patent No. 5,518,918

*March of Dimes does not endorse

specific products or brands.

March of Dimes is a registered trademark of the March of Dimes Foundation.



Six child-resistant blister packs of 5 tablets and 5 capsules each - NDC 0178-0816-30
Retail Carton



CITRANATAL BLOOM DHA

iron, folic acid, cyanocobalamin, ascorbic acid, docusate sodium and dha kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0178-0816
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0178-0816-30	30 in 1 CARTON	01/18/2018	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1		1
Part 2		1

Part 1 of 2

PRENATAL

iron, folic acid, cyanocobalamin, ascorbic acid, and docusate sodium tablet, coated

Product Information

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
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	12 ug
FERROUS GLUCONATE (UNII: U1B1I423Z) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	1.5 mg
IRON PENTACARBONYL (UNII: 6WQ62TAQ6Z) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	88.5 mg
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg

Inactive Ingredients

Ingredient Name	Strength
MAGNESIUM SILICATE (UNII: 9B9691B2N9)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
ETHYL VANILLIN (UNII: YC9ST449YJ)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
DIMETHYLAMINOETHYL METHACRYLATE - BUTYL METHACRYLATE - METHYL METHACRYLATE COPOLYMER (UNII: 905HNO1SIH)	
POVIDONE (UNII: FZ989GH94E)	

Product Characteristics

Color	green (Coated Tablet)	Score	score with uneven pieces
Shape	RECTANGLE (Modified Rectangle)	Size	9mm
Flavor		Imprint Code	CB;blank
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/22/2018	

Part 2 of 2

DHA

dha capsule, liquid filled

Product Information

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CRYPTHECODINIUM COHNII DHA OIL (UNII: 8ZJ335A17J) (CRYPTHECODINIUM COHNII DHA OIL - UNII:8ZJ335A17J)	CRYPTHECODINIUM COHNII DHA OIL	300 mg in 300 mg

Inactive Ingredients

Ingredient Name	Strength
ICOSAPENT (UNII: AAN7QOV9EA)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
ROSEMARY (UNII: IJ67X351P9)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
TOCOPHEROL (UNII: R0ZB2556P8)	

Product Characteristics

Color	brown (Soft gelatin capsule)	Score	no score
Shape	CAPSULE (Soft gelatin capsule)	Size	23mm
Flavor		Imprint Code	none
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		01/18/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/18/2018	

Labeler - Mission Pharmacal Company (008117095)

Registrant - Mission Pharmacal Company (922772689)

Establishment

Name	Address	ID/FEI	Business Operations
Mission Pharmacal Company		927726893	manufacture(0178-0816)

Revised: 4/2020

Mission Pharmacal Company