

**CITRANATAL ASSURE- ascorbic acid, calcium citrate, iron, vitamin d, dl- alpha-tocopherol acetate, thiamine, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, iodine, zinc, copper, docusate sodium, doconexent and icosapent
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 Assure[®]

Rx Prenatal Vitamin Tablet and 300 mg DHA Capsule

DESCRIPTION

CitraNatal Assure[®] 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,

coated, oval multivitamin/mineral tablet. The tablet is debossed "0891" 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 capsule contains:

Vitamin C (Ascorbic acid)	120 mg
Calcium (Calcium citrate)	124 mg
Iron (Carbonyl iron, ferrous gluconate)	35 mg
Vitamin D ₃ (Cholecalciferol)	400 IU
Vitamin E (dl-alpha tocopheryl acetate)	30 IU
Thiamin (Vitamin B ₁)	3 mg
Riboflavin (Vitamin B ₂)	3.4 mg
Niacinamide (Vitamin B ₃)	20 mg
Vitamin B ₆ (Pyridoxine HCl)	25 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 750 mg Algal Oil)	300 mg
Eicosapentaenoic Acid (EPA)	Not more than 0.750 mg

Other ingredients in DHA gelatin capsule: Gelatin, sunflower oil, glycerin, caramel color, sunflower lecithin, rosemary extract, tocopherols, ascorbyl palmitate.

INDICATIONS

CitraNatal Assure[®] 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

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.

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

STORAGE

Store at 20–25°C (68–77°F)

NOTICE

Contact with moisture can discolor or erode the tablet.

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

51062R1120

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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Six child-resistant blister packs of 5 tablets and 5 capsules each - NDC 0178-0891-30

CitraNatal Assure Retail Blister Pack
NDC 0178-0891-30

DHA CAPSULES Distributed by: MISSION PHARMACAL COMPANY San Antonio, TX 78230 1355	RX ONLY CITRANATAL ASSURE® MISSION PHARMACAL COMPANY San Antonio, TX 78230 1355
DHA CAPSULE 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.	NDC 0178-0891-30 LOT: 0X000X EXP: 00/0000 CITRANATAL ASSURE® TABLET WARNING: Accidental overdose of time-releasing 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.
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Retail Carton

CITRANATAL ASSURE

ascorbic acid, calcium citrate, iron, vitamin d, dl- alpha- tocopherol acetate, thiamine, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, iodine, zinc, copper, docusate sodium, doconexent and icosapent kit

Product Information

Product Type

HUMAN PRESCRIPTION DRUG

Item Code (Source)

NDC:0178-0891

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0178-0891-30	30 in 1 CARTON	04/30/2014	
1		1 in 1 BLISTER PACK; Type 1: Convenience Kit of Co-Package		

Quantity of Parts

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

Part 1 of 2

PRENATAL VITAMIN

ascorbic acid, calcium citrate, iron, vitamin d, dl- alpha- tocopherol acetate, thiamine, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, iodine, zinc, copper 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
IRON (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)	IRON	35 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	400 [iU]
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1) (ALPHA-TOCOPHEROL - UNII:H4N855PNZ1)	ALPHA-TOCOPHEROL	30 [iU]
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	25 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
IODINE (UNII: 9679TC07X4) (IODINE - UNII:9679TC07X4)	IODINE	150 ug
ZINC (UNII: J41CSQ7QDS) (ZINC - UNII:J41CSQ7QDS)	ZINC	25 mg
COPPER (UNII: 789U1901C5) (COPPER - UNII:789U1901C5)	COPPER	2 mg
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg
THIAMINE (UNII: X66NSO3N35) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	3 mg
CALCIUM CITRATE (UNII: MLM29U2X85) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CITRATE ANHYDROUS	124 mg

Inactive Ingredients

Ingredient Name	Strength
POVIDONE K30 (UNII: U725QWY32X)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MAGNESIUM SILICATE (UNII: 9B9691B2N9)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SHELLAC (UNII: 46N107B71O)	
VANILLIN (UNII: CH1530446X)	

Product Characteristics

Color	white	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	0891
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/19/2008	

Part 2 of 2

DHA

doconexent and icosapent capsule

Product Information

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOCONEXENT (UNII: ZAD9OKH9JC) (DOCONEXENT - UNII:ZAD9OKH9JC)	DOCONEXENT	300 mg
ICOSAPENT (UNII: AAN7QOV9EA) (ICOSAPENT - UNII:AAN7QOV9EA)	ICOSAPENT	0.75 mg

Inactive Ingredients

Ingredient Name	Strength
GELATIN (UNII: 2G86QN327L)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
GLYCERIN (UNII: PDC6A3C0OX)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	

ROSEMARY (UNII: IJ67X351P9)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	

Product Characteristics

Color	orange (caramel color)	Score	no score
Shape	CAPSULE	Size	23mm
Flavor		Imprint Code	
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/19/2008	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/30/2014	

Labeler - Mission Pharmacal Company (008117095)

Registrant - Mission Pharmacal Company (927726893)

Establishment

Name	Address	ID/FEI	Business Operations
Mission Pharmacal Company		927726893	manufacture(0178-0891)

Revised: 1/2024

Mission Pharmacal Company