

CITRANATAL ASSURE - ascorbic acid, calcium citrate, iron, vitamin d, .alpha.-tocopherol acetate, dl-, 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.

**CitraNatalAssure®
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 "0893" on one side and is blank on the other. The essential fatty acid DHA capsule is clear and contains an amber to light/dark orange semi-solid mixture.

Each prenatal capsule contains:

Vitamin C (Ascorbic acid)	120 mg
Calcium (Calcium citrate)	125 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)	300 mg
Eicosapentaenoic Acid (EPA)	Not more than 0.750 mg

DHA is contained in the oil derived from microalgae.

Other ingredients in DHA gelatin capsule: Gelatin, Glycerin USP, Water.

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.

CAUTION

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

DOSAGE AND ADMINISTRATION

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

Store at controlled room temperature.

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 0178-0893-30**

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

50289

C02 Rev 010090

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

www.missionpharmacal.com

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Ferr-Ease™

Dual-iron delivery

Trademark of Mission Pharmacal Company

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

life's **DHA™**

HEALTHY BRAIN, EYES, HEART

Trademark of Martek Biosciences Corporation

U.S. Patent No. 5,407,957

U.S. Patent No. 5,492,938

*March of Dimes does not endorse
specific products or brands.

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

PRINCIPAL DISPLAY PANEL - Six 5-day Blister Pack Carton

Rx Only

NDC 0178-0893-30

*Its gentle nature
is its strength*

CitraNatalAssure®

Rx Prenatal Vitamin Tablet and 300 mg DHA Capsule

An Rx prenatal
vitamin and
omega-3 (DHA)
derived from an
all natural
plant source

march of dimes®

Mission Pharmacal is a proud
supporter of the March of Dimes.*

CONTAINS

Six 5-day Blister Packs

Mission®

PHARMACAL

Rx Only
NDC 0178-0893-30

CitraNatalAssure.

Rx Prenatal Vitamin Tablet and 300 mg DHA Capsule

Child-Resistant Blister Packaging

KO Area

Rx Only
NDC 0178-0893-30

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Rx Prenatal Vitamin Tablet and 300 mg DHA Capsule

An Rx prenatal
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march of dimes

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CONTAINS
Six 5-day Blister Packs

Mission
PHARMACAL

CitraNatalAssure.

Rx Prenatal Vitamin Tablet and 300 mg DHA Capsule

- Gentle calcium citrate and iron, plus a stool softener for your delicate GI system
- Natural, plant-based DHA (NO mercury, no PCB) for your baby's healthy development

*Its gentle nature
is its strength*

Contains
Stool
Softener





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 "0893" on one side and is blank on the other. The essential fatty acid DHA capsule is clear and contains an amber to light/dark orange semi-solid mixture.

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Each DHA gelatin capsule contains:

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CitraNatal Assure[®]

Rx Prenatal Vitamin Tablet and 300 mg DHA Capsule

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.

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

DOSAGE AND ADMINISTRATION: One tablet and one capsule daily or as directed by a physician.

Store at controlled room temperature.

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 0178-0893-30

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

50289
C02 Rev 010090



Trademark of Mission Pharmaceutical Company

CitraNatal Assure DHA Retail
9 11/20/09

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.



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

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



Trademark of Martek Biosciences Corporation
U.S. Patent No. 5,407,957
U.S. Patent No. 5,492,938

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Mission Citi
AC 50289R100

CITRANATAL ASSURE

ascorbic acid, calcium citrate, iron, vitamin d, .alpha.-tocopherol acetate, dl-, 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:0178-0893
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0178-0893-30	6 in 1 CARTON		
1		1 in 1 BLISTER PACK		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1		5
Part 2		5

Part 1 of 2

PRENATAL VITAMIN

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

Product Information

Route of Administration	ORAL
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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 - UNII:SY7Q814VUP)	calcium citrate	125 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]
Thiamine (UNII: X66NSO3N35) (Thiamine - UNII:X66NSO3N35)	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	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

Inactive Ingredients

Ingredient Name	Strength
POVIDONE K30 (UNII: U725QWY32X)	
Croscarmellose Sodium (UNII: M28OL1HH48)	
Titanium Dioxide (UNII: 15FIX9V2JP)	
Magnesium Silicate (UNII: 9B9691B2N9)	
Magnesium Stearate (UNII: 70097M6I30)	
Shellac (UNII: 46N107B71O)	
VANILLIN (UNII: CHI530446X)	

Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	0893
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)	
Glycerin (UNII: PDC6A3C0OX)	
Water (UNII: 059QF0K00R)	

Product Characteristics

Color	ORANGE (clear, amber to light/dark orange)	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		11/19/2008	

Labeler - Mission Pharmacal Company (008117095)

Establishment

Name	Address	ID/FEI	Business Operations
Accucaps Industries Ltd		248441727	MANUFACTURE

Establishment

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