CITRANATAL ASSURE - ascorbic acid, calcium citrate, iron, vitamin d, .alpha.-tocopherol acetate, dl-, thiamine, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, iodine, zinc, copper, docus ate sodium, doconexent and icos apent 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-EaseTM, 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.

Eash assessed assessed assessed		
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 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.

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-EaseTM

Dual-iron delivery

Trademark of Mission Pharmacal Company U.S. Patent No. 6,521,247

life's **DHA**TM

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

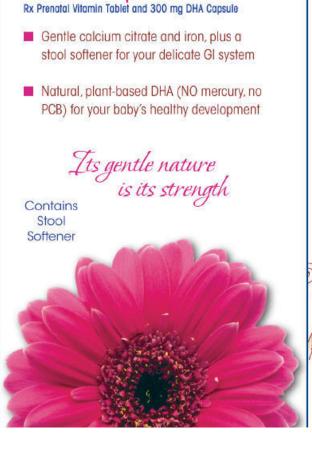
An Rx prenatal vitamin and omega-3 (DHA) derived from an all natural plant source

march of dimes $^{\mathbb{R}}$

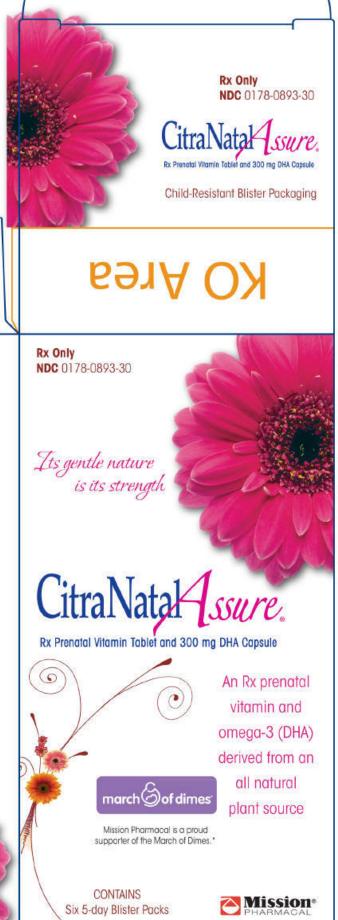
Mission Pharmacal is a proud supporter of the March of Dimes.*

CONTAINS Six 5-day Blister Packs

Mission[®] PHARMACAL



Citra Nata 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.

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)		mg
Vitamin B ₆ (Pyridoxine HCI)	25	mg
Folic Acid	1	mg
Iodine (Potassium iodide)	150	meg
Zinc (Zinc oxide)	25	mg
Copper (Cupric oxide)	2	mg
Docusate Sodium	50	mg
Each DHA gelatin capsule contains:		10110
Docosahexaenoic Acid (DHA)	300	mg
Eicosapentaenoic Acid (EPA)Not more than 0		mg
DHA is contained in the oil derived from microaldae		125

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.



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

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.

C02 Rev 010090



aNatal Assure DHA Retail

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: MISSION PHARMACAL COMPANY San Antonio, TX USA 78230 1355

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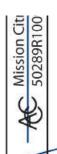
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Trademark of Martek Biosciences Corporatio U.S. Patent No. 5,407,957 U.S. Patent No. 5,492,938

"March of Dimes does not endorse specific products or brands. March of Dimes is a registered trademark of the March of Dimes Foundation.



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

Packaging

i uchuşing			
# 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		

Ouantity 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

н		
	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 - UNII:SY7Q814VUP)	calcium citrate	125 mg	
Iron (UNII: E1UOL152H7) (Iron - UNII:E1UOL152H7)	Iro n	35 mg	
Cholecalciferol (UNII: 1C6 V77QF41) (Cholecalciferol - UNII:1C6 V77QF41)	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)	Ribo fla vin	3.4 mg	
Niacinamide (UNII: 25X51I8RD4) (Niacinamide - UNII:25X51I8RD4)	Niacinamide	20 mg	
Pyridoxine Hydrochloride (UNII: 68Y4CF58BV) (Pyridoxine - UNII:KV2JZ1BI6Z)	Pyrido xine Hydro chlo ride	25 mg	
Folic Acid (UNII: 935E97BOY8) (Folic Acid - UNII:935E97BOY8)	Folic Acid	1 mg	
Iodine (UNII: 9679TC07X4) (Iodine - UNII:9679TC07X4)	Io dine	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	
PO VIDO NE K30 (UNII: U725QWY32X)		
Croscarmellose Sodium (UNII: M28 OL 1HH48)		
Titanium Dioxide (UNII: 15FIX9V2JP)		
Magnesium Silicate (UNII: 9B9691B2N9)		
Magnesium Stearate (UNII: 70097M6I30)		
Shellac (UNII: 46 N10 7B71O)		
VANILLIN (UNII: CHI530446X)		

Product Characteristics			
Color	WHITE	Score	no score
Shape	OVAL	Size	20 mm
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	
DO CO NEXENT (UNII: ZAD9 OKH9 JC) (DOCONEXENT - UNII: ZAD9 OKH9 JC)	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: 059QF0KO0R)		

Product Characteristics			
Color	ORANGE (clear, amber to light/dark orange)	Score	no score
Shape	CAPSULE	Size	23mm
Flavor		Imprint Code	
Contains			

ı	Marketing Information				
ı	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	