

**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.*

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**CitraNatal Assure<sup>®</sup>**

**Rx Prenatal Vitamin Tablet and 300 mg DHA Capsule**

## **DESCRIPTION**

CitraNatal Assure<sup>®</sup> is a prescription prenatal/postnatal multivitamin/mineral tablet with Ferr-Ease<sup>®</sup>, 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.

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**Each prenatal capsule contains:**

Vitamin C (Ascorbic acid)	120 mg
Calcium (Calcium citrate)	124 mg
Iron (Carbonyl iron, ferrous gluconate)	35 mg
Vitamin D <sub>3</sub> (Cholecalciferol)	400 IU
Vitamin E (dl-alpha tocopheryl acetate)	30 IU
Thiamin (Vitamin B <sub>1</sub> )	3 mg
Riboflavin (Vitamin B <sub>2</sub> )	3.4 mg
Niacinamide (Vitamin B <sub>3</sub> )	20 mg
Vitamin B <sub>6</sub> (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

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

## INDICATIONS

CitraNatal Assure<sup>®</sup> 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<sub>12</sub> 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<sup>®</sup> 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

<b>DHA CAPSULES</b> Distributed by: MISSION PHARMACAL COMPANY San Antonio, TX 78230 1355	<b>RX ONLY</b> <b>CITRANATAL ASSURE<sup>®</sup></b> MISSION PHARMACAL COMPANY San Antonio, TX 78230 1355
<b>DHA CAPSULE</b> <b>WARNING:</b> 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.	<b>NDC 0178-0891-30</b> <b>LOT: 0X000X EXP: 00/0000</b> <b>CITRANATAL ASSURE<sup>®</sup> TABLET</b> <b>WARNING:</b> Accidental overdose of time-sensitive 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.
<b>DHA CAPSULE</b> <b>WARNING:</b> 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.	<b>NDC 0178-0891-30</b> <b>LOT: 0X000X EXP: 00/0000</b> <b>CITRANATAL ASSURE<sup>®</sup> TABLET</b> <b>WARNING:</b> Accidental overdose of time-sensitive 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
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	120 mg
<b>IRON</b> (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)	IRON	35 mg
<b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	400 [iU]
<b>ALPHA-TOCOPHEROL</b> (UNII: H4N855PNZ1) (ALPHA-TOCOPHEROL - UNII:H4N855PNZ1)	ALPHA-TOCOPHEROL	30 [iU]
<b>RIBOFLAVIN</b> (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	3.4 mg
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	20 mg
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	25 mg
<b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
<b>IODINE</b> (UNII: 9679TC07X4) (IODINE - UNII:9679TC07X4)	IODINE	150 ug
<b>ZINC</b> (UNII: J41CSQ7QDS) (ZINC - UNII:J41CSQ7QDS)	ZINC	25 mg
<b>COPPER</b> (UNII: 789U1901C5) (COPPER - UNII:789U1901C5)	COPPER	2 mg
<b>DOCUSATE SODIUM</b> (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg
<b>THIAMINE</b> (UNII: X66NSO3N35) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	3 mg
<b>CALCIUM CITRATE</b> (UNII: MLM29U2X85) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CITRATE ANHYDROUS	124 mg

## Inactive Ingredients

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

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	0891
<b>Contains</b>			

## 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

<b>Route of Administration</b>	ORAL
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## Active Ingredient/Active Moiety

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

## Inactive Ingredients

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

<b>ROSEMARY</b> (UNII: IJ67X351P9)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>ASCORBYL PALMITATE</b> (UNII: QN83US2B0N)	

<b>Product Characteristics</b>			
<b>Color</b>	orange (caramel color)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	23mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

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

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

**Labeler** - Mission Pharmacal Company (008117095)

**Registrant** - Mission Pharmacal Company (927726893)

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