

**CITRANATAL DHA- vitamin c, calcium, iron, vitamin d3, vitamin e, thiamin, riboflavin, niacinamide, vitamin b6, folic acid, iodine, zinc, copper, docusate sodium**

**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® DHA**

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.

**DESCRIPTION**

CitraNatal® 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 an essential fatty acid. The prenatal vitamin is a white, scored, oval multi-vitamin/mineral tablet. The tablet is debossed “CN 1” on one side and is blank on the other. The essential fatty acid DHA soft gel is caramel colored and contains a light yellow to orange semi-solid mixture.

**Each prenatal tablet contains :**

Vitamin C (Ascorbic acid)	120 mg
Calcium (Calcium citrate)	124 mg
Iron (Carbonyl iron, ferrous gluconate)	27 mg
Vitamin D3 (Cholecalciferol)	400 IU
Vitamin E (dl-alpha tocopheryl acetate)	30 IU
Thiamin (Vitamin B1)	3 mg
Riboflavin (Vitamin B2)	3.4 mg
Niacinamide (Vitamin B3)	20 mg
Vitamin B6 (Pyridoxine)	20 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 soft gel contains :**

Docosahexaenoic Acid (DHA, 40% from 625 mg Algal Oil)	250 mg
Eicosapentaenoic Acid (EPA)	Not more than 0.625 mg
Other ingredients in DHA soft gel: High oleic sunflower oil, sunflower lecithin, rosemary extract, tocopherols, ascorbyl palmitate.	

**INDICATIONS**

CitraNatal<sup>®</sup> 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.

## **CONTRAINDICATIONS**

This product is contraindicated in patients with a known hypersensitivity to any of the ingredients.

### **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 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.

## **HOW SUPPLIED**

Six child-resistant blister packs of 5 tablets and 5 soft gels each - **NDC** 0178-0894-30.

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

**Please consult** your health care provider with any dietary concerns.

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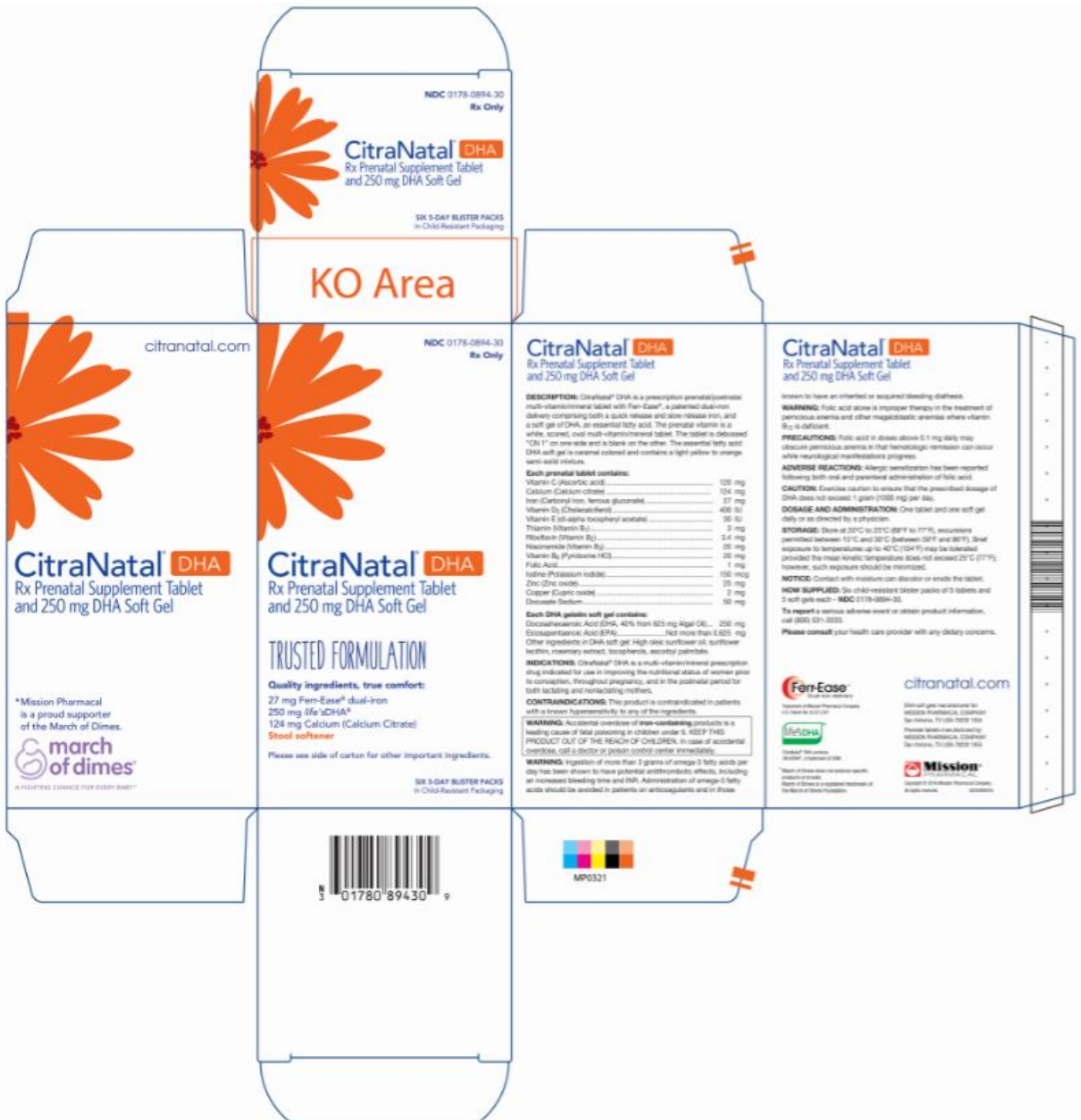
DHA soft gels manufactured for:  
MISSION PHARMACAL COMPANY  
San Antonio, TX USA 78230 1355  
Prenatal tablets manufactured by:

MISSION PHARMACAL COMPANY  
 San Antonio, TX USA 78230 1355

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Citranatal DHA  
 Rx Prenatal Vitamin Tablet  
 and 250 mg DHA Soft Gel  
 Carton

NDC 0178-0894-30



KO Area

[citranatal.com](http://citranatal.com)

NDC 0178-0894-30  
 Rx Only

**Citranatal DHA**  
 Rx Prenatal Supplement Tablet  
 and 250 mg DHA Soft Gel

**DESCRIPTION:** Citranatal® 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 white, round, oval multi-vitamin/mineral tablet. The tablet is debossed "CN 1" on one side and is blank on the other. The essential fatty acid DHA soft gel is coral colored and contains a light yellow to orange semi-solid mixture.

**Each prenatal tablet contains:**

Vitamin C (Ascorbic Acid)	100 mg
Calcium Calcium citrate	104 mg
Iron (Carbonyl iron, ferrous gluconate)	27 mg
Vitamin E2 (Cholecalciferol)	400 IU
Vitamin E3 (alpha tocopherol acetate)	30 IU
Vitamin B12 (Cyanocobalamin)	3 mg
Riboflavin (Vitamin B2)	3.4 mg
Niacinamide (Vitamin B3)	25 mg
Vitamin B6 (Pyridoxine HCl)	25 mg
Folic Acid	1 mg
Iodine (Potassium iodide)	150 mcg
Zinc (Zinc oxide)	25 mg
Copper (Copper oxide)	2 mg
Demethyl Selenium	50 mcg

**Each DHA gelatin soft gel contains:**  
 Docosahexaenoic Acid (DHA, 42% from 625 mg Algal Oil)..... 250 mg  
 Eicosapentaenoic Acid (EPA)..... Not more than 5.625 mg  
 Other ingredients in DHA soft gel: High oleic sunflower oil, sunflower lecithin, mannary extract, tocopherols, acetylul palmitate.

**INDICATIONS:** Citranatal® 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 non-lactating 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 anti-thrombotic effects, including an increased bleeding time and INR. Administration of omega-3 fatty acids should be avoided in patients on anticoagulants and in those

**Citranatal DHA**  
 Rx Prenatal Supplement Tablet  
 and 250 mg DHA Soft Gel

**WARNINGS:** 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 5.1 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).

**USAGE AND ADMINISTRATION:** 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 final kinetic temperature does not exceed 25°C (77°F); however, such exposures should be minimized.

**NOTICE:** Contact with moisture can dissolve or erode the tablet.

**HOW SUPPLIED:** Six child-resistant blister packs of 5 tablets and 5 soft gels each - NDC 0178-0894-30.

To report a serious adverse event or obtain product information, call (800) 421-3033.

Please consult your health care provider with any dietary concerns.



[citranatal.com](http://citranatal.com)

Soft gel gels manufactured by  
 MISSION PHARMACAL COMPANY  
 San Antonio, TX 78230 1355  
 Blister packs manufactured by  
 MISSION PHARMACAL COMPANY  
 San Antonio, TX 78230 1355



Blister Pack

<p><b>DHA SOFT GELS</b></p> <p>Distributed by: MISSION PHARMACAL COMPANY San Antonio, TX 78230 1355</p> <p><b>DHA SOFT GEL</b></p> <p><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 VNR. 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.</p>	<p style="text-align: right;"><b>RX ONLY</b></p> <p><b>CITRANATAL® RX</b> MISSION PHARMACAL COMPANY San Antonio, TX 78230 1355</p> <p><b>NDC 0178-0894-30</b> <b>LOT: 0X000X EXP: 00/0000</b> <b>CITRANATAL® RX TABLET</b></p> <p><b>WARNING:</b> 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.</p>	<p><b>DHA SOFT GELS</b></p> <p>Distributed by: MISSION PHARMACAL COMPANY San Antonio, TX 78230 1355</p> <p><b>DHA SOFT GEL</b></p> <p><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 VNR. 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.</p>	<p style="text-align: right;"><b>RX ONLY</b></p> <p><b>CITRANATAL® RX</b> MISSION PHARMACAL COMPANY San Antonio, TX 78230 1355</p> <p><b>NDC 0178-0894-30</b> <b>LOT: 0X000X EXP: 00/0000</b> <b>CITRANATAL® RX TABLET</b></p> <p><b>WARNING:</b> 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.</p>
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**CITRANATAL DHA**

vitamin c, calcium, iron, vitamin d3, vitamin e, thiamin, riboflavin, niacinamide, vitamin b6, folic acid, iodine, zinc, copper, docusate sodium kit

**Product Information**

Product Type

HUMAN PRESCRIPTION DRUG

Item Code (Source)

NDC:0178-0894

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0178-0894-30	30 in 1 CARTON	05/22/2014	
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 VITAMIN

vitamin c, calcium, iron, vitamin d3, vitamin e, thiamin, riboflavin, niacinamide, vitamin b6, folic acid, iodine, zinc, copper, docusate sodium tablet

### 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
VITAMIN D (UNII: 9VU1K144GP) (CHOLECALCIFEROL - UNII:1C6V77QF41)	VITAMIN D	400 [iU]
IRON (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)	IRON	27 mg
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) (.ALPHA.-TOCOPHEROL - UNII:H4N855PNZ1)	.ALPHA.-TOCOPHEROL	30 [iU]
THIAMINE (UNII: X66NSO3N35) (THIAMINE ION - UNII:4ABT0J945J)	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	20 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
POTASSIUM IODIDE (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	POTASSIUM IODIDE	150 mg
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	25 mg
CUPRIC OXIDE (UNII: V1XJQ704R4) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	2 mg
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg
CALCIUM CITRATE (UNII: MLM29U2X85) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CITRATE	124 mg

### Inactive Ingredients

Ingredient Name	Strength
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MAGNESIUM SILICATE (UNII: 9B9691B2N9)	
SHELLAC (UNII: 46N107B71O)	
ETHYL VANILLIN (UNII: YC9ST449YJ)	

VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)

### Product Characteristics

Color	white (white to off white)	Score	no score
Shape	OVAL (modified oval)	Size	20mm
Flavor		Imprint Code	CN;1
Contains			

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/22/2014	

## 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	250 mg
ICOSAPENT (UNII: AAN7QOV9EA) (ICOSAPENT - UNII:AAN7QOV9EA)	ICOSAPENT	0.625 mg

### Inactive Ingredients

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

### Product Characteristics

Color	brown (caramel)	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
DIETARY SUPPLEMENT		05/22/2014	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/22/2014	

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

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

## Establishment

Name	Address	ID/FEI	Business Operations
Mission Pharmacal Company		927726893	manufacture(0178-0894)

Revised: 7/2020

Mission Pharmacal Company