

CITRANATAL ESSENCE- 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 Essence™

Rx Prenatal Vitamin Tablet and 300 mg DHA Capsule

DESCRIPTION

CitraNatal Essence™ is a prescription prenatal/postnatal multi-vitamin/ mineral tablet with Ferr-Ease®, a 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, coated, oval multi-vitamin/mineral tablet. The tablet is debossed “0864” on one side and is blank on the other. The essential fatty acid DHA soft gel is oblong, transparent, and caramel colored.

INDICATIONS

CitraNatal Essence™ 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.

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.

51065R0420

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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www.missionpharmaceutical.com

Ferr-Ease[®]

Dual-iron delivery

Trademark of Mission Pharmacal Company

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

life's **DHA**®

life'sDHA is a trademark of DSM.

U.S. Patent No. 7,579,174

U.S. Patent No. 7,732,170

U.S. Patent No. 5,518,918

*March of Dimes does not endorse

specific products or brands.

March of Dimes is a registered trademark

of the March of Dimes Foundation.

Six child-resistant blister packs of 5 tablets and 5 capsules each - NDC 0178-0864-30

Retail Carton



CITRANATAL ESSENCE

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:0178-0864
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:0178-0864-30	30 in 1 CARTON	07/07/2020	
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
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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
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:KV2JZ1B16Z)	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
THIAMINE (UNII: X66NSO3N35) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	3 mg
CALCIUM CITRATE (UNII: MLM29U2X85) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CITRATE ANHYDROUS	140 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	0864
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		07/07/2020	

Part 2 of 2

DHA

doconexent and icosapent capsule

Product Information

Route of Administration ORAL

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		07/07/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		07/07/2020	

Labeler - Mission Pharmacal Company (008117095)**Registrant** - Mission Pharmacal Company (927726893)**Establishment**

Name	Address	ID/FEI	Business Operations
Mission Pharmacal Company		927726893	manufacture(0178-0864)

Revised: 7/2020

Mission Pharmacal Company