

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

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® Rx

DESCRIPTION

CitraNatal® Rx is a prenatal/postnatal multi-vitamin/mineral tablet with Ferr-Ease®, a patented dual-iron delivery comprising both a quick release and slow release iron. CitraNatal® Rx is a white, oval tablet debossed “CN 1” on one side and blank on the other.

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

INDICATIONS

CitraNatal® Rx 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.

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

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 daily or as directed by a physician.

STORAGE

Store at 20-25°C (68-77°F) [See USP controlled room temperature].

NOTICE

Contact with moisture can discolor or erode the tablet.

HOW SUPPLIED

Bottles of 90 tablets each - NDC 0178-0858-90.

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

MISSION PHARMACAL COMPANY L085890
San Antonio, TX USA 78230 1355 C01 Rev 004140

CitraNatal® Rx Label
NDC: 0178-0858-90

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Iron (Carbonyl iron, ferrous gluconate).....	27 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).....	20 mg
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L085890
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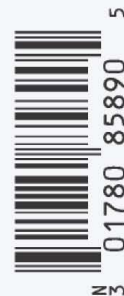
NDC 0178-0858-90

Rx Only

CitraNatal® Rx
Rx Prenatal Vitamin Tablet

Dual-Iron with
Calcium Citrate,
Multi-vitamins
and Minerals

90 Tablets



CITRANATAL RX

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

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0178-0858
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 CATION - UNII:2M83C4R6ZB)	CALCIUM CITRATE	124 mg
IRON (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)	IRON	27 mg
VITAMIN D (UNII: 9VU1KI44GP) (CHOLECALCIFEROL - UNII:1C6V77QF41)	VITAMIN D	400 [iU]
.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:KV2JZ1B16Z)	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

Inactive Ingredients

Ingredient Name	Strength
POVIDONES (UNII: FZ989GH94E)	132.2 mg
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	56.1 mg
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	30.6 mg
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	30.5 mg
MAGNESIUM SILICATE (UNII: 9B9691B2N9)	10.38 mg
MAGNESIUM STEARATE (UNII: 70097M6I30)	5.1 mg
SHELLAC (UNII: 46N107B71O)	2.59 mg
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	1.98 mg
ETHYL VANILLIN (UNII: YC9ST449YJ)	.66 mg
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	.15 mg

Product Characteristics

Color	WHITE	Score	2 pieces
Shape	OVAL	Size	10mm
Flavor		Imprint Code	CN;1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:0178-0858-90	90 in 1 BOTTLE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
Unapproved drug other		08/11/2014		

Labeler - Mission Pharmacal Company (008117095)

Registrant - Mission Pharmacal Company (927726893)

Establishment

Name	Address	ID/FEI	Business Operations
Mission Pharmacal Company		927726893	MANUFACTURE(0178-0858)

Revised: 8/2014

Mission Pharmacal Company