

**CITRANATAL B-CALM- ascorbic acid, calcium citrate, iron, cholecalciferol,
pyridoxine hydrochloride, and folic acid**
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 B-Calm ®

Rx Prenatal Vitamin and two 25 mg each B₆ tablets

A prescription prenatal supplement with 1 mg folic acid and a high level of vitamin B₆ which may act as an antiemetic.

DESCRIPTION

CitraNatal B-Calm[®] is a prescription prenatal multivitamin/mineral tablet with B₆, along with two vitamin B₆ tablets. The prenatal tablet contains Ferr-Ease[®], a patented dual iron delivery comprising both a quick release and slow release iron. The prenatal tablet is white, coated, modified oval, and is debossed with "0832" on one side and is blank on the other. The B₆ 25 mg tablets are white to off-white, uncoated, round, and are debossed with "B" on one side and "6" on the other.

Each prenatal tablet contains:

Vitamin C (Ascorbic acid)	120 mg
Calcium (Calcium citrate)	120 mg
Iron (Carbonyl iron, Ferrous gluconate)	20 mg
Vitamin D ₃ (Cholecalciferol)	400 IU
Vitamin B ₆ (Pyridoxine HCl)	25 mg
Folic Acid	1 mg

Each vitamin B₆ tablet contains:

Vitamin B ₆ (Pyridoxine HCl)	25 mg
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INDICATIONS

CitraNatal B-Calm[®] 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. CitraNatal B-Calm[®] may be used in conjunction with a physician prescribed regimen to help minimize pregnancy related nausea and vomiting.

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 AND ALL DRUGS 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.

PRECAUTION

Folic acid in doses above 0.1 mg daily may obscure pernicious anemia, in that hematologic remission can occur while neurological manifestations remain progressive.

ADVERSE REACTIONS

Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

DOSAGE AND ADMINISTRATION

One tablet every eight hours, beginning with "Tablet 1", or as directed by a physician.

Store at controlled room temperature.

NOTICE: Contact with moisture can discolor or erode tablets.

HOW SUPPLIED

Six child-resistant blister packs of 5 multivitamin/multimineral tablets and 10 vitamin B₆ tablets each - **NDC0178-0832-30**.

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

50310 C01 Rev 0820

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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PRINCIPAL DISPLAY PANEL - Blister Pack Carton

Rx Only

NDC0178-0832-30

The gentle option for additional B₆

CitraNatalB-Calm[®]

Rx Prenatal Vitamin and two 25 mg each Vitamin B₆ tablets

A prescription prenatal supplement with 1 mg of folic acid and a high level of vitamin B₆ which may act as an antiemetic.

CONTAINS

Six 5-day Blister Packs



CITRANATAL B-CALM

ascorbic acid, calcium citrate, iron, cholecalciferol, pyridoxine hydrochloride, and folic acid kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0178-0832
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:0178-0832-30	6 in 1 CARTON	06/18/2012	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	6 BLISTER PACK	30
Part 2	6 BLISTER PACK	60

Part 1 of 2

PRENATAL VITAMIN

ascorbic acid, calcium citrate, iron, cholecalciferol, pyridoxine hydrochloride, and folic acid tablet, film coated

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	25 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	120 mg
CALCIUM CITRATE (UNII: MLM29U2X85) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CITRATE ANHYDROUS	120 mg
IRON (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)	IRON	20 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	400 [iU]

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	174.3 mg
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	55 mg
POVIDONE (UNII: FZ989GH94E)	30 mg
HYPROMELLOSES (UNII: 3NXW29V3WO)	18.9 mg
IRON PENTACARBONYL (UNII: 6WQ62TAQ6Z)	17.5 mg
MAGNESIUM SILICATE (UNII: 9B9691B2N9)	9 mg
MAGNESIUM STEARATE (UNII: 70097M6I30)	2.2 mg
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	0.25 mg
DIMETHYLAMINOETHYL METHACRYLATE - BUTYL METHACRYLATE - METHYL METHACRYLATE COPOLYMER (UNII: 905HNO1SIH)	

Product Characteristics

Color	white	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	0832
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		5 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/18/2012	

Part 2 of 2

VITAMIN B6

pyridoxine hydrochloride tablet

Product Information

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	25 mg

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	B;6
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/18/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/18/2012	

Labeler - Mission Pharmacal Company (008117095)

Establishment

Name	Address	ID/FEI	Business Operations
Nutra-Med Packaging, Inc.		022004902	pack(0178-0832)

Establishment

Name	Address	ID/FEI	Business Operations
Mission Pharmacal Company		927726893	manufacture(0178-0832)