

**CITRANATAL B-CALM- ascorbic acid, calcium citrate, iron pentacarbonyl, cholecalciferol, pyridoxine hydrochloride, 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](#).*

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**CitraNatal® B-Calm**

**Rx Prenatal Vitamin with two 25 mg each Vitamin B<sub>6</sub> tablets**

A prescription prenatal supplement with 1 mg folic acid and a high level of vitamin B<sub>6</sub> which may act as an antiemetic.

**DESCRIPTION**

CitraNatal® B-Calm™ is a prescription prenatal multivitamin/mineral tablet with a high level of B<sub>6</sub>, along with two vitamin B<sub>6</sub> tablets. The prenatal tablet is white, coated, modified oval, and is debossed with "0866" on one side and is blank on the other. The B<sub>6</sub> 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)	125 mg
Iron (Carbonyl iron)	20 mg
Vitamin D <sub>3</sub> (Cholecalciferol)	400 IU
Vitamin B <sub>6</sub> (Pyridoxine HCl)	25 mg
Folic Acid	1 mg

**Each vitamin B<sub>6</sub> tablet contains:**

Vitamin B <sub>6</sub> (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 B<sub>12</sub> 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 B<sub>6</sub> tablets each -  
NDC 0178-0866-30.

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

50307 C01 REV 010090

MISSION PHARMACAL COMPANY  
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**[www.missionpharmacal.com](http://www.missionpharmacal.com)**

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## **PRINCIPAL DISPLAY PANEL**

Rx Only

NDC 0178-0866-30

*The gentle option for  
additional B<sub>6</sub>*

**CitraNatal<sup>®</sup> B-Calm**

**Rx Prenatal Vitamin with two 25 mg each Vitamin B<sub>6</sub> tablets**

A prescription  
prenatal supplement  
with 1 mg of folic  
acid and a high level  
of vitamin B<sub>6</sub> which  
may act as an  
antiemetic.

**march of dimes<sup>®</sup>**

Mission Pharmacal is a proud supporter of the March of Dimes.<sup>®</sup>

CONTAINS  
Six 5-day Blister Packs

**Mission<sup>®</sup>**  
PHARMACAL



## CITRANATAL B-CALM

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

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0178-0866
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**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0178-0866-30	5 in 1 CARTON		
1		1 in 1 BLISTER PACK		

**Quantity of Parts**

Part #	Package Quantity	Total Product Quantity
Part 1		5
Part 2		10

**Part 1 of 2****PRENATAL VITAMIN**

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

**Product Information**

<b>Route of Administration</b>	ORAL
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**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>calcium citrate</b> (UNII: MLM29U2X85) (calcium - UNII:SY7Q814VUP)	calcium citrate	125 mg
<b>Iron Pentacarbonyl</b> (UNII: 6WQ62TAQ6Z) (Iron Pentacarbonyl - UNII:6WQ62TAQ6Z)	Iron Pentacarbonyl	20 mg
<b>Cholecalciferol</b> (UNII: 1C6V77QF41) (Cholecalciferol - UNII:1C6V77QF41)	Cholecalciferol	400 [iU]
<b>Pyridoxine Hydrochloride</b> (UNII: 68Y4CF58BV) (Pyridoxine - UNII:KV2JZ1B16Z)	Pyridoxine Hydrochloride	25 mg
<b>folic acid</b> (UNII: 935E97BOY8) (folic acid - UNII:935E97BOY8)	folic acid	1 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>Polyethylene Glycol</b> (UNII: 3WJQ0SDW1A)	
<b>Cellulose, Microcrystalline</b> (UNII: OP1R32D61U)	
<b>Povidone</b> (UNII: FZ989GH94E)	
<b>Hypromelloses</b> (UNII: 3NXW29V3WO)	
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP)	
<b>Magnesium Silicate</b> (UNII: 9B9691B2N9)	
<b>Magnesium Stearate</b> (UNII: 70097M6130)	

Vitamin A Palmitate (UNII: 1D1K0N0VVC)

### Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL (modified)	Size	19mm
Flavor		Imprint Code	0866
Contains			

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		02/10/2010	

## 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:KV2JZ1B16Z)	Pyridoxine Hydrochloride	25 mg

### Inactive Ingredients

Ingredient Name	Strength
Cellulose, Microcrystalline (UNII: OP1R32D61U)	
Povidone (UNII: FZ989GH94E)	
Magnesium Stearate (UNII: 70097M6I30)	

### Product Characteristics

Color	WHITE (off-white)	Score	no score
Shape	ROUND	Size	6mm
Flavor		Imprint Code	B;6
Contains			

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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Unapproved drug other		02/10/2010	
<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		02/10/2010	

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

### Establishment

Name	Address	ID/FEI	Business Operations
Mission Pharmacal Company		927726893	MANUFACTURE

### Establishment

Name	Address	ID/FEI	Business Operations
Nutra-Med Packaging Inc.		022004902	PACK

Revised: 5/2010

Mission Pharmacal Company