

**CITRANATAL HARMONY- calcium citrate, iron pentacarbonyl, cholecalciferol, alpha-tocopherol, dl-, pyridoxine hydrochloride, folic acid, docusate sodium, and doconexent capsule, gelatin coated**  
**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® Harmony™**  
**Rx Prenatal Vitamin Gel Cap**

**DESCRIPTION**

CitraNatal® Harmony™ is a prescription prenatal/postnatal multivitamin/mineral soft gelatin capsule. The prenatal vitamin is a purple, opaque soft gelatin capsule containing a greenish-gray liquid to semi-solid fill. The capsule is printed "0812" in white ink.

**Each prenatal capsule contains:**

Calcium (Calcium citrate)	100 mg	Vitamin B <sub>6</sub> (Pyridoxine HCl)	25 mg
Iron (Carbonyl iron)	27 mg	Folic Acid	1 mg
Vitamin D <sub>3</sub> (Cholecalciferol)	400 IU	Docusate Sodium	50 mg
Vitamin E (dl-alpha tocopheryl acetate)	30 IU	Docosahexaenoic Acid (DHA)	250 mg

DHA is contained in the oil derived from microalgae.

**INDICATIONS**

CitraNatal® Harmony™ 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 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.

**CAUTION:** Exercise caution to ensure that the prescribed dosage of DHA does not exceed 1 gram (1000 mg) per day.

## **DOSAGE AND ADMINISTRATION**

One capsule daily or as directed by a physician.

Store at controlled room temperature.

**NOTICE:** Contact with moisture can discolor or erode the capsule.

## **HOW SUPPLIED**

Bottles of 30 capsules each - **NDC 0178-0812-30.**

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

life's**DHA**<sup>™</sup>

Trademark of Martek Biosciences Corporation

U.S. Patent No. 5,407,957

U.S. Patent No. 5,492,938

Manufactured for:

**MISSION PHARMACAL COMPANY**

San Antonio, TX USA 78230 1355

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

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## **PRINCIPAL DISPLAY PANEL - 30 Capsule Bottle Carton**

*The one-pill solution  
for gentle prenatal nutrition*

**Rx Only**

**NDC 0178-0812-05**

**CitraNatal<sup>®</sup> Harmony<sup>™</sup>**

Rx Prenatal Vitamin Gel Cap

- Convenient, one-dose prenatal nutrition  
in a vanilla-scented gel cap

- Gentle calcium citrate and carbonyl iron,  
plus a stool softener and natural,  
plant-based DHA

life's**DHA**™

HEALTHY BRAIN, EYES, HEART

**5-DAY STARTER PACK**

*In Child-Resistant Packaging*

Sample-Not For Sale

Contains

Stool Softener

**Mission®**

PHARMACAL

Save up to \$100

before, during and after  
your pregnancy on your  
prenatal vitamin

CitraNatal Harmony  
Rx Prenatal Vitamin Gel Cap



Look for valuable coupon inside

The one-pill solution  
for gentle prenatal nutrition

Rx Only NDC 0178-0812-05

# CitraNatal Harmony™

Rx Prenatal Vitamin Gel Cap

- Convenient, one-dose prenatal nutrition in a vanilla-scented gel cap
- Gentle calcium citrate and carbonyl iron, plus a stool softener and natural, plant-based DHA



**5-DAY STARTER PACK**  
In Child-Resistant Packaging  
Sample-Not For Sale

Contains  
Stool Softener



# CitraNatal Harmony™

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50290 C01 Rev.006090

DHA is contained in the oil derived from microalgae.

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**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 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.

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U.S. Patent No. 5,407,967  
U.S. Patent No. 5,492,938

Manufactured for:  
MISSION PHARMACAL COMPANY  
San Antonio, TX USA 78230 1355

[www.missionpharmaceutical.com](http://www.missionpharmaceutical.com)

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## CITRANATAL HARMONY

calcium citrate, iron pentacarbonyl, cholecalciferol, alpha-tocopherol, dl-, pyridoxine hydrochloride, folic acid, docusate sodium, and doconexent capsule, gelatin coated

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:0178-0812
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Calcium citrate</b> (UNII: MLM29U2X85) (Calcium - UNII:S Y7Q814VUP)	Calcium citrate	100 mg
<b>Iron pentacarbonyl</b> (UNII: 6WQ62TAQ6Z) (Iron - UNII:E1UOL152H7)	Iron pentacarbonyl	27 mg
<b>Cholecalciferol</b> (UNII: 1C6V77QF41) (Cholecalciferol - UNII:1C6V77QF41)	Cholecalciferol	400 [iU]
<b>Alpha-tocopherol, DL-</b> (UNII: 7QWA1RIO01) (Alpha-tocopherol, DL- - UNII:7QWA1RIO01)	Alpha-tocopherol, DL-	30 [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
<b>Docusate Sodium</b> (UNII: F05Q2T2JA0) (Docusate - UNII:M7P27195AG)	Docusate Sodium	50 mg
<b>Doconexent</b> (UNII: ZAD9OKH9JC) (Doconexent - UNII:ZAD9OKH9JC)	Doconexent	250 mg

### Product Characteristics

<b>Color</b>	PURPLE (opaque)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	25mm
<b>Flavor</b>		<b>Imprint Code</b>	812
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0178-0812-30	1 in 1 CARTON		
1		30 in 1 BOTTLE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		04/27/2010	

**Labeler** - MISSION PHARMACAL COMPANY (008117095)

## Establishment

Name	Address	ID/FEI	Business Operations
Accucaps Industries Ltd.		248441727	MANUFACTURE

## Establishment

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

Revised: 5/2010

MISSION PHARMACAL COMPANY