CITRANATAL HARMONY 3.0- 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 <sup>®</sup> (Calcium citrate, Iron pentacarbonyl, Cholecalciferol, .Alpha.-Tocopherol, DI-, Pyridoxine hydrochloride, Folic Acid, Docusate Sodium, and Doconexent) capsules for oral use.

## **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.

#### **DESCRIPTION**

CitraNatal Harmony <sup>®</sup> 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 "0796" in white ink.

Each prenatal capsule contains:					
Calcium (Calcium	104	Vitamin B <sub>6</sub> (Pyridoxine HCl)	25		
citrate)	mg	Vicalitiii D 6(1 yi idoxiile i ici)	mg		
Iron (Ferrous fumarate, 27		Folic Acid	1		
carbonyl iron)	mg	Tolic Acid	mg		
Vitamin D	400	Docusate Sodium	50		
<sub>3</sub> (Cholecalciferol)	IU	Docusate Socialii	mg		
Vitamin E (dl-alpha	30	Docosahexaenoic Acid (DHA 40%	260		
tocopheryl acetate)	IU	from 650 mg Algal Oil)	mg		

## **INDICATIONS**

CitraNatal Harmony <sup>®</sup> 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 contraindictated in patients with a known hypersensitivity to any of the ingredients.

#### 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  $_{12}$ 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 0178-0796-30

To report a serious adverse event or obtain product information, call (210) 696-8400 Please consult your health care provider with any dietary concerns.

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

## NDC 0178-0796-30



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 30 SOFT GELS 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.

HOW SUPPLIED: Bottles of 30 soft gels each -NDC 0178-0796-30.

To report a serious adverse event or obtain product information, call (800) 298-1087.

Please consult your health care provider with any dietary concerns.

citranatal.com



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CitraNatal Harmony soft gels are MADE IN CANADA for: MISSION PHARMACAL COMPANY



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## **CITRANATAL HARMONY 3.0**

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

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0178-0796
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CALCIUM CITRATE (UNII: MLM29U2X85) (CALCIUM CATION - UNII: 2M83C4R6ZB)	CALCIUM CITRATE ANHYDROUS	104 mg	
IRON (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)	IRON	27 mg	
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	400 [iU]	
.ALPHATOCOPHEROL (UNII: H4N855PNZ1) (.ALPHATOCOPHEROL - UNII:H4N855PNZ1)	.ALPHATOCOPHEROL	30 [iU]	
PYRIDOXINE (UNII: KV2JZ1BI6Z) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	25 mg	
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg	
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg	
DOCONEXENT (UNII: ZAD9OKH9JC) (DOCONEXENT - UNII:ZAD9OKH9JC)	DOCONEXENT	260 mg	

Inactive Ingredients	
Ingredient Name	Strength
GELATIN (UNII: 2G86QN327L)	

Product Characteristics			
Color	purple (opaque)	Score	no score
Shape	CAPSULE	Size	25mm
Flavor		Imprint Code	0796

## Contains

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	IDC:0178-0796- 80	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/21/2014	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/21/2014	
otilei			

# Labeler - Mission Pharmacal Company (008117095)

Registrant - Mission Pharmacal Company (927726893)

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