

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.

CitraNatal Harmony®
Rx Prenatal Vitamin
Gel Cap

Rx Only

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 "0798" in white ink.

Each prenatal capsule contains:

Calcium (Calcium citrate)	104 mg
Iron (Carbonyl iron)	30 mg
Vitamin D ₃ (Cholecalciferol)	400 IU
Vitamin E (dl-alpha tocopheryl acetate)	30 IU
Vitamin B ₆ (Pyridoxine HCl)	25 mg
Folic Acid	1 mg
Docusate Sodium	50 mg
Docosahexaenoic Acid (DHA 40% from 650 mg Algal Oil)	260 mg

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 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.

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 0178-0798-30.**

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

life's**DHA**[™]

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

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MADE IN CANADA

L079830 C01 Rev 009110

PRINCIPAL DISPLAY PANEL - 30 Capsule Bottle Label

NDC 0178-0798-30

Rx Only

CitraNatal Harmony®

Rx Prenatal Vitamin
Gel Cap

30 Capsules

march of dimes®

Mission Pharmacal is a proud
supporter of the March of Dimes.*

Mission®

PHARMACAL

NDC 0178-0798-30 Rx Only

CitraNatal Harmony®

Rx Prenatal Vitamin
Gel Cap

30 Capsules

march of dimes
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Mission
PHARMACAL

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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

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0178-0798
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Calcium citrate (UNII: MLM29U2X85) (Calcium - UNII:S Y7Q814VUP)	Calcium citrate	104 mg
Iron pentacarbonyl (UNII: 6WQ62TAQ6Z) (Iron - UNII:E1UOL152H7)	Iron pentacarbonyl	30 mg
Cholecalciferol (UNII: 1C6V77QF41) (Cholecalciferol - UNII:1C6V77QF41)	Cholecalciferol	400 [iU]
.Alpha.-Tocopherol, DI- (UNII: 7QWA1RIO01) (.Alpha.-Tocopherol, DI- - UNII:7QWA1RIO01)	.Alpha.-Tocopherol, DI-	30 [iU]
Pyridoxine hydrochloride (UNII: 68Y4CF58BV) (Pyridoxine - UNII:KV2JZ1B16Z)	Pyridoxine hydrochloride	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

Product Characteristics

Color	PURPLE (opaque)	Score	no score
Shape	CAPSULE	Size	25mm
Flavor		Imprint Code	0798
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0178-0798-30	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		01/15/2012	

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: 1/2012

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