

CITRANATAL HARMONY 2.1- 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.

These highlights do not include all the information needed to use CitraNatal Harmony[®] safely and effectively. See full prescribing information for CitraNatal Harmony[®].

CitraNatal Harmony[®] (Calcium citrate, Iron pentacarbonyl, Cholecalciferol, .Alpha.-Tocopherol, DL-, Pyridoxine hydrochloride, Folic Acid, Docusate Sodium, and Doconexent) capsules for oral use.

Initial U.S. Approval: 2012

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[®] 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 "0797" in white ink.

Each prenatal capsule contains:

Calcium (Calcium citrate)	104 mg	Vitamin B ₆ (Pyridoxine HCl)	25 mg
Iron (Carbonyl iron)	29 mg	Folic Acid	1 mg
Vitamin D ₃ (Cholecalciferol)	400 IU	Docusate Sodium	50 mg
Vitamin E (d -alpha tocopheryl acetate)	30 IU	Docosahexaenoic Acid (DHA 40% from 650 mg Algal Oil)	265 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

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 0178-0797-30

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

CitraNatal Sample Carton
NDC 0178-0797-06

before, during, and after your pregnancy on your prenatal vitamin

up to **\$100** Save

Look for valuable savings card inside

Working together for stronger, healthier babies
Mission Pharmacal is a proud supporter of the March of Dimes

Contains
5-DAY STARTER PACK
In a child-resistant packaging sample-size for sale



Convenient, one-dose prenatal nutrition
In a vanilla-scented gel cap
Gentle sodium citrate and gamma-oryzanol, plus a stool softener and natural, plant-based DHA

CitraNatal Harmony
Rx Prenatal Vitamin Gel Cap

The one-pill solution for gentle prenatal nutrition

Rx Only NDC 0178-0797-05

CitraNatal Harmony
Rx Prenatal Vitamin Gel Cap

CitraNatal Harmony
Rx Prenatal Vitamin Gel Cap

#1 prenatal vitamin brand*

Look for valuable savings card inside

up to **\$100** Save
before, during, and after your pregnancy on your prenatal vitamin



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 "0797" in white ink.

Each prenatal capsule contains:			
Calcium (Calcium citrate)	104 mg	Vitamin B6 (Pyridoxine HCl)	25 mg
Iron (Carbonyl iron)	23 mg	Folic Acid	1 mg
Vitamin D3 (Cholecalciferol)	400 IU	Docusate Sodium	50 mg
Vitamin E (d-alpha-tocopheryl acetate)	30 IU	Docosahexaenoic Acid (DHA 48% from 650 mg Algal Oil)	265 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 non-lactating 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 neurologic 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.

DOSE AND ADMINISTRATION: One capsule daily or as directed by a physician.

MADE IN CANADA

Store at controlled room temperature.

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

HOW SUPPLIED: Bottles of 30 capsules each - NDC 0178-0797-05.

To report a serious adverse event or obtain product information, call (314) 658-6400.

Please consult your health care provider with any dietary concerns.

LifeDHA is a trademark of B&B. U.S. Patent No. 6,491,307 U.S. Patent No. 6,481,818

*Source: Healthcare Analytics FIRST Prescription database, accessed 9/18/2012. *March of Dimes does not endorse specific products or brands. March of Dimes is a registered trademark of the March of Dimes Foundation.

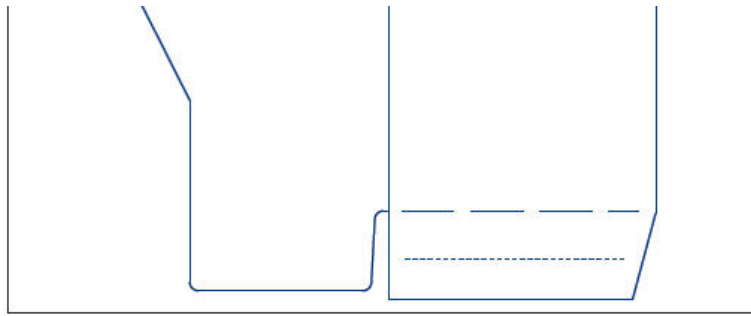


Manufactured for: MISSION PHARMACAL COMPANY San Antonio, TX USA 78230 1355 missionpharmaco.com

Copyright © 2012 Mission Pharmacal Company. All rights reserved.



020395 031 Rev 01/12



CitraNatal Label
NDC 0178-0797-05

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.

NDC 0178-0797-05 Rx Only

CitraNatal Harmony®

Rx Prenatal Vitamin Gel Cap

5 Capsules
In Child-Resistant Packaging

Sample - Not for sale



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 0178-0797-30

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

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

Made in Canada L079705 C01 Rev 011120

CitraNatal Starter Pack

CitraNatal Label
NDC 0178-0797-30

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 "0797" in white ink.

Each prenatal capsule contains:

Calcium (Calcium citrate).....	104 mg
Iron (Carbonyl Iron).....	29 mg
Vitamin D ₃ (Cholecalciferol).....	400 IU
Vitamin E (d-alpha tocopheryl acetate)	30 IU
Vitamin B ₉ (Pyridoxine HCl).....	25 mg
Folic Acid.....	1 mg
Docosahexaenoic Acid (DHA).....	50 mg
40% from 680 mg Algal Oil.....	265 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.

NDC 0178-0797-30 Rx Only

CitraNatal Harmony®

Rx Prenatal Vitamin Gel Cap

30 Capsules



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.

HOW SUPPLIED: Bottles of 30 capsules each - NDC 0178-0797-30.

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

*March of Dimes does not endorse specific products or brands. March of Dimes is a registered trademark of the March of Dimes Foundation.

LifeSdHA® is a trademark of SDMA, LLC. Patent No. 6,887,887. U.S. Patent No. 6,888,838.

MISSION PHARMACAL

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

Copyright © 2012 Mission Pharmacal Company. All rights reserved.

MADE IN CANADA

L079730 C01 Rev 011120

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:0178-0797
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CALCIUM CITRATE (UNII: MLM29U2X85) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	104 mg
IRON (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)	IRON	29 mg

Inactive Ingredients

Ingredient Name	Strength
CHOLECALCIFEROL (UNII: 1C6V77QF41)	400 [iU]
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	30 [iU]
PYRIDOXINE (UNII: KV2JZ1B16Z)	25 mg
FOLIC ACID (UNII: 935E97BOY8)	1 mg
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	50 mg
DOCONEXENT (UNII: ZAD9OKH9JC)	265 mg

Product Characteristics

Color	purple (opaque)	Score	no score
Shape	CAPSULE	Size	25mm
Flavor		Imprint Code	0797
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0178-0797-05	1 in 1 CARTON	01/21/2013	03/21/2014
1		5 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0178-0797-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/21/2013	03/21/2014

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/21/2013	

Labeler - Mission Pharmacal Company (008117095)

Registrant - Mission Pharmacal Company (927726893)

Establishment

Name	Address	ID/FEI	Business Operations
Accucaps Industries Limited		248441727	manufacture(0178-0797)

Revised: 5/2019

Mission Pharmacal Company