

IMPORTANT ANNOUNCEMENT:

A change in one electronic database may limit your patients' access to important prescription prenatal vitamins

Dear Doctor,

We at Mission Pharmacal Company ("Mission Pharmacal") wish to make you aware that First Databank ("FDB"), an electronic drug coding database, has made an incorrect decision to either delete prescription prenatal vitamins from the FDB database or reclassify prescription prenatal vitamins into a new category on the FDB database. **Many prenatal vitamins, previously classified as prescription products in the FDB database, now fall under a new "Q" category** in FDB's database for products that are neither prescription drugs nor medical devices, such as dietary supplements. One result of such incorrect action by FDB is that the CitraNatal® prescription prenatal vitamins of Mission Pharmacal have been wrongfully deleted by FDB from its database.

FDB's action in this matter could lead to **certain denials of insurance coverage for prenatal vitamins**. Moreover, FDB's decision **contradicts statements from the U.S. Food and Drug Administration ("FDA")**, which recognizes the importance of prenatal vitamins containing folic acid, and has stated that physicians *can and do* write prescriptions for prenatal vitamins.

It is our belief that expectant mothers deserve to have their nutritional needs evaluated by a qualified, expert medical professional and receive the highest standard of care throughout their pregnancy. However, **FDB's action could prevent mothers-to-be from getting the nutritional support** that's critical to the healthy development of their babies.

Please be aware that all of the other drug coding databases have not made any change to the classification of prescription prenatal vitamins from Mission Pharmacal. These other drug coding databases, such as Medi-Span and others, are used in numerous national and regional pharmacies, including Walgreens, WalMart, H.E.B. and others, which means that your patients should not have any problems filling your prescriptions for the CitraNatal® brand of prescription prenatal vitamins made by Mission Pharmacal at such pharmacies.



In a recent independent survey by the March of Dimes:

50% of women reported that they took prescription prenatal vitamins during their current/last pregnancy, and 88% said it was covered by their insurance.¹



Why prescription prenatal vitamins are so important:

CitraNatal® prescription prenatal vitamins are formulated with optimal levels of nutrients, such as folic acid, iron, vitamin B₁₂, vitamin C, and DHA, among others. In addition, many of our CitraNatal® prenatal vitamin formulations also contain vitamin B₆ and a stool softener.



Did you know?

Up to 70% of the 3,000 neural tube defects that occur each year in the U.S. could be prevented if all women of childbearing potential took a prenatal vitamin containing folic acid.^{2,3}

References: 1. March of Dimes. Fewer than half of U.S. women take recommended vitamins prior to pregnancy, according to March of Dimes new Prenatal Health & Nutrition Survey. <https://www.marchofdimes.org/news/fewer-than-half-of-u-s-women-take-recommended-vitamins-prior-to-pregnancy-according-to-march-of-dimes-new-prenatal-health-nutrition-survey.aspx>. Published September 19, 2017. Accessed August 2020. 2. ACOG Committee on Practice Bulletins—Obstetrics. ACOG Practice Bulletin 187: clinical management guidelines for obstetrician-gynecologists. *Obstet & Gynecol.* 2017;130(6):e279-e290. doi:10.1097/AOG.0000000000002412. 3. Centers for Disease Control and Prevention (CDC). Folic Acid & Neural Tube Defects: An Overview. <https://www.cdc.gov/ncbddd/birthdefectscount/basics.html>. Accessed August 2020.

INDICATIONS: CitraNatal Harmony®, CitraNatal Assure®, CitraNatal B-Calm®*, CitraNatal® 90 DHA and CitraNatal Bloom® are multi-vitamin/mineral prescription drugs 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.

Important Safety Information

CONTRAINDICATIONS: These products are 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 THESE PRODUCTS OUT OF THE REACH OF CHILDREN. In case of accidental overdose, call a doctor or poison control center immediately.

Please see page 2 for additional Important Safety Information. Please also see pages 3 and 4 for full Prescribing Information, including Precautions and Adverse Reactions.

CitraNatal® Rx Nutritional will continue to be available – regardless of changes by FDB



We're doing our part to support mothers-to-be – nutritionally and financially

We at Mission Pharmacal are taking measures to provide all patients with access to our prenatal nutritional supplements.



- For patients with commercial insurance coverage, we offer a savings card allowing patients to pay as little as \$25*, which we will continue to provide and can be downloaded from the citr natal.com website.
- CitraNatal® also continues to be available through managed care plans like Caremark and Express Scripts®, as well as through CVS Caremark® mail order for Caremark members. State Medicaid plans will continue to operate under current conditions, based on plan and member benefit coverage.

*Up to \$50 savings limit per month. Subject to eligibility. Restrictions apply. See back of card for details.



Let's continue to support expectant mothers and their babies

The first recommendations regarding folic acid supplementation were made back in 1992 by the U.S. Public Health Service.² Mission Pharmacal stands with you in supporting these recommendations and ensuring every mother-to-be has access to the nutritional support she and her baby need.

Have questions or concerns about this change by FDB?



If you have questions about this change by FDB or access to CitraNatal® Rx Nutritional tablets for specific patients, please speak with one of our Customer Service agents.

Contact Mission Pharmacal Customer Service at:
(800) 531-3333
Monday-Wednesday, 7:00 AM to 5:30 PM CST,
and Thursday, 7:00 AM to 5:00 PM CST

Reference: 2. ACOG Committee on Practice Bulletins—Obstetrics. ACOG Practice Bulletin 187: clinical management guidelines for obstetrician-gynecologists. *Obstet & Gynecol.* 2017;130(6):e279-e290. doi:10.1097/AOG.0000000000002412.

Important Safety Information (cont'd)

WARNING: More than 3 grams total intake per day of omega-3 fatty acids from all sources, including both food and supplements (like Docosahexaenoic Acid [DHA] and Eicosapentaenoic Acid [EPA]), have 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.[†]

[†]CitraNatal B-Calm® and CitraNatal Bloom® do not contain DHA or EPA.

WARNING: Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B₁₂ is deficient.

See full Prescribing Information on pages 3 and 4 for additional information, including Precautions and Adverse Reactions.



CitraNatal **HARMONY**

Rx Prenatal Soft Gel

DESCRIPTION: CitraNatal Harmony® is a prescription prenatal/postnatal multi-vitamin/mineral soft gel with Ferr-Ease®, a dual-iron delivery comprising both a quick release and slow release iron, and DHA, an essential fatty acid. The prenatal vitamin is a purple, opaque soft gel containing a greenish-gray liquid to semi-solid fill. The soft gel is printed “0796” in white ink.

Each prenatal soft gel contains:

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
Calcium (calcium citrate).....	104 mg
Iron (carbonyl iron, ferrous fumarate)	27 mg
Docosate Sodium.....	50 mg
Docosahexaenoic Acid (DHA, 40% from 650 mg algal oil)	260 mg

INDICATIONS: CitraNatal Harmony is a multi-vitamin/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 soft gel daily or as directed by a physician.

STORAGE: Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized.

NOTICE: Contact with moisture can discolor or erode the soft gel.

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 **ASSURE**

Rx Prenatal Tablet and 300 mg DHA Soft Gel

DESCRIPTION: CitraNatal Assure® is a prescription prenatal/postnatal multi-vitamin/mineral tablet with Ferr-Ease®, a dual-iron delivery comprising both a quick release and slow release iron, and a soft gel of DHA, an essential fatty acid. The prenatal vitamin is a white, coated, oval multi-vitamin/mineral tablet. The tablet is debossed “0891” on one side and is blank on the other. The essential fatty acid DHA soft gel is oblong, transparent, and caramel colored.

Each prenatal tablet contains:

Vitamin C (ascorbic acid).....	120 mg
Calcium (calcium citrate).....	124 mg
Iron (carbonyl iron, ferrous gluconate).....	35 mg
Vitamin D ₃ (cholecalciferol)	400 IU
Vitamin E (dl-alpha tocopheryl acetate)	30 IU
Thiamin (vitamin B ₁)	3 mg
Riboflavin (vitamin B ₂)	3.4 mg
Niacinamide (vitamin B ₃)	20 mg
Vitamin B ₆ (pyridoxine HCl).....	25 mg
Folic Acid.....	1 mg
Iodine (potassium iodide)	150 mcg
Zinc (zinc oxide).....	25 mg
Copper (cupric oxide).....	2 mg
Docosate Sodium.....	50 mg

Each DHA soft gel contains:

Docosahexaenoic Acid (DHA, 40% from 750 mg algal oil)	300 mg
Eicosapentaenoic Acid (EPA)	Not more than 0.75 mg
Other ingredients in DHA soft gel: Gelatin, glycerin, high oleic sunflower oil, contains 2% or less: water, caramel color, tocopherols, rosemary extract, and ascorbyl palmitate.	

INDICATIONS: CitraNatal Assure® is a multi-vitamin/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 tablet and one soft gel daily or as directed by a physician.

STORAGE: Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized.

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

HOW SUPPLIED: Six child-resistant blister packs of 5 tablets and 5 soft gels each - NDC 0178-0891-30.

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 **B-CALM**

Rx Prenatal Tablet and two 25 mg each Vitamin B₆ Tablets

DESCRIPTION: CitraNatal B-Calm® is a prescription prenatal/postnatal multi-vitamin/mineral tablet with B₆, along with two vitamin B₆ tablets. The prenatal tablet contains Ferr-Ease®, a dual-iron delivery comprising both a quick release and slow release iron. The prenatal tablet is a white, coated, modified oval, and is debossed “0832” on one side and is blank on the other. The B₆ 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)	120 mg
Iron (carbonyl iron, ferrous gluconate).....	20 mg
Vitamin D ₃ (cholecalciferol)	400 IU
Vitamin B ₆ (pyridoxine HCl).....	25 mg
Folic Acid.....	1 mg

Each vitamin B₆ tablet contains:

Vitamin B ₆ (pyridoxine HCl).....	25 mg
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INDICATIONS: CitraNatal B-Calm® is a multi-vitamin/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 PRODUCT 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 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.

DOSAGE AND ADMINISTRATION: One tablet every eight hours, beginning with “Tablet 1”, or as directed by a physician.

STORAGE: Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized.

NOTICE: Contact with moisture can discolor or erode tablets.

HOW SUPPLIED: Six child-resistant blister packs of 5 multi-vitamin/mineral tablets and 10 vitamin B₆ tablets each - NDC 0178-0832-30.

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® 90 DHA

Rx Prenatal Tablet and 300 mg DHA Soft Gel

DESCRIPTION: CitraNatal® 90 DHA is a prescription prenatal/postnatal multi-vitamin/mineral tablet with Ferr-Ease®, a dual-iron delivery comprising both a quick release and slow release iron, and a soft gel of DHA, an essential fatty acid. The prenatal vitamin is a white, coated, oval multi-vitamin/mineral tablet. The tablet is debossed “CN 90” on one side and “0821” on the other. The essential fatty acid DHA soft gel is oblong, transparent, and caramel colored.

Each prenatal tablet contains:

Vitamin C (ascorbic acid).....	120 mg
Calcium (calcium citrate).....	159 mg
Iron (carbonyl iron, ferrous gluconate).....	90 mg
Vitamin D ₃ (cholecalciferol)	400 IU
Vitamin E (dl-alpha tocopheryl acetate)	30 IU
Thiamin (vitamin B ₁)	3 mg
Riboflavin (vitamin B ₂).....	3.4 mg
Niacinamide (vitamin B ₃).....	20 mg
Vitamin B ₆ (pyridoxine HCl).....	20 mg
Folic Acid.....	1 mg
Iodine (potassium iodide)	150 mcg
Zinc (zinc oxide).....	25 mg
Copper (cupric oxide).....	2 mg
Docusate Sodium.....	50 mg

Each DHA soft gel contains:
 Docosahexaenoic Acid
 (DHA, 40% from 750 mg algal oil) 300 mg
 Eicosapentaenoic Acid (EPA)Not more than 0.75 mg
 Other ingredients in DHA soft gel: Gelatin, glycerin, high oleic sunflower oil, contains 2% or less: water, caramel color, tocopherols, rosemary extract, and ascorbyl palmitate.

INDICATIONS: CitraNatal® 90 DHA is a multi-vitamin/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 tablet and one soft gel daily or as directed by a physician.

STORAGE: Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized.

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

HOW SUPPLIED: Six child-resistant blister packs of 5 tablets and 5 soft gels each - NDC 0178-0821-30.

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 BLOOM®

Rx Prenatal Tablet

DESCRIPTION: CitraNatal Bloom® is a prescription prenatal/postnatal multi-vitamin/mineral tablet with Ferr-Ease®, a dual-iron delivery comprising both a quick release and slow release iron. CitraNatal Bloom is a green, modified rectangle shaped, film-coated tablet, debossed with “CB” on one side and blank on the other.

Each prenatal tablet contains:

Iron (carbonyl iron, ferrous gluconate).....	90 mg
Folic Acid.....	1 mg
Vitamin B ₁₂ (cyanocobalamin)	12 mcg
Vitamin C (ascorbic acid).....	120 mg
Docusate Sodium.....	50 mg

Inactive Ingredients: Povidone, croscarmellose sodium, acrylic resin, color added, FD&C Yellow No. 5, magnesium stearate, magnesium silicate, FD&C Blue No. 1, polyethylene glycol, vitamin A palmitate, ethyl vanillin.

INDICATIONS: CitraNatal Bloom is a multi-vitamin/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: 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.

DOSAGE AND ADMINISTRATION: One tablet daily or as directed by a physician.

STORAGE: Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized.

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

HOW SUPPLIED: Bottles of 30 tablets each – NDC 0178-0813-30.

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

Please consult your health care provider with any dietary concerns.

citr natal.com

CitraNatal Harmony, CitraNatal Assure, and CitraNatal 90 DHA contain life'sDHA®, a trademark of DSM.



DHA soft gels and CitraNatal Harmony soft gels are MADE IN CANADA for: MISSION PHARMACAL COMPANY San Antonio, TX USA 78230 1355

Prenatal tablets manufactured by: MISSION PHARMACAL COMPANY San Antonio, TX USA 78230 1355

CitraNatal Harmony, CitraNatal Assure, CitraNatal B-Calm, CitraNatal 90 DHA, and CitraNatal Bloom contain Ferr-Ease®.



Trademark of Mission Pharmacal Company

