

Gesticare[®]DHA *has a new NDC number.*

Delayed-Release Prenatal Multi-vitamin/Mineral Tablets
with DHA and Choline

Physicians will prescribe Gesticare DHA as usual, but prescriptions must be filled with the new NDC Code indicated below effective immediately. Package size/ Description, Dosage Form, and WAC of Gesticare DHA remain unchanged.

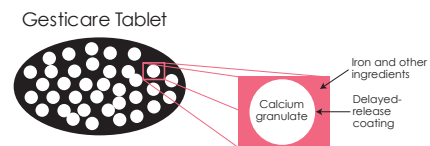
New NDC Code and Item Numbers

NDC Number	AmerisourceBergen	Cardinal Health	McKesson
New: 18860-0253-30	005-439	4243440	1207802
Old: 18860-0353-30	816-280	4119541	1413673

Important considerations for prenatal vitamin absorption

- Prenatal vitamins have an absorption problem. The mutual interference in the GI tract between calcium and iron reduces iron absorption by as much as 50%.¹
- Gesticare DHA iron is released immediately into the stomach while a coated layer protects the calcium from being released until it reaches the small intestine.²

Novel delayed-release of both iron and calcium²



How Gesticare DHA is supplied

NDC Number	Product Name	Package Size/ Description	Dosage Form	WAC	Effective Date
18860-0253-30	Gesticare w/DHA	30 tablets per box 6 blister cards with 5 Gesticare tablets and 5 DHA gelatin capsules each Prenatal multi-vitamin/mineral pH-dependent delayed-release tablets	Tablet + Capsule	\$41.25	09/15/09

Indications and Usage

Gesticare DHA is indicated for use in improving the nutritional status of women throughout pregnancy and in the postnatal period for both lactating and nonlactating mothers. Gesticare DHA is also beneficial in improving nutritional status of women prior to conception.

Contraindications

This product is contraindicated in patients with a known hypersensitivity to any of the ingredients.

Warnings

Ingestion of more than 3 grams of omega-3 fatty acids per day has been shown to have potential antithrombotic effects, including 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.

1. Ahn E, Kapur B, Koren G. Iron bioavailability in prenatal multivitamin supplements with separated and combined iron and calcium. *J Obstet Gynaecol Can.* 2004;26:809-814. 2. Data on file. Azur Pharma, Inc.

Delayed-release delivery of the nutrients expectant mothers need most

Each tablet contains:

Ingredient	Dose
Vitamin B1 (Thiamin Mononitrate)	3 mg
Vitamin B2 (Riboflavin Universal)	3 mg
Vitamin B6 (Pyridoxine HCl)	50 mg
Vitamin B12 (Cyanocobalamin)	8 µg
Vitamin C (Ascorbic Acid)	120 mg
Niacin (Niacinamide)	20 mg
Folic Acid	1 mg
Iron (Ferrous Fumarate)	27 mg
Calcium (Calcium Carbonate)	200 mg
Vitamin D (Vitamin D3)	410 IU
Vitamin E (Vitamin E Acetate)	30 IU
Iodine (Potassium Iodide)	150 µg
Zinc (Zinc Oxide)	15 mg
Choline (Choline Bitartrate)	55 mg

Each DHA gelatin capsule contains:

Ingredient	Dose
Docosahexaenoic Acid (DHA)	250 mg
Eicosapentaenoic Acid (EPA)	Not more than 0.625 mg

DHA is an **omega-3 fatty acid**. The DHA in Gesticare® DHA is derived from the oils of microalgae.

Other ingredients in the DHA gelatin capsule: Gelatin (bovine), Glycerine USP, High Oleic Sunflower Oil, Ascorbyl Palmitate, Tocopherols.

Patent Status

U.S. Patents 5,407,957 & 5,492,938. Patent application #20070128272 pending.

Indications and Usage

Gesticare DHA is indicated for use in improving the nutritional status of women throughout pregnancy and in the postnatal period for both lactating and nonlactating mothers. Gesticare DHA is also beneficial in improving the nutritional status of women prior to conception.

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 reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

Warnings

Ingestion of more than 3 grams of omega-3 fatty acids per day has been shown to have potential antithrombotic effects, including 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.

Precautions

Folic acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive.

Adverse Reactions

Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

Dosage and Administration

One Gesticare delayed-release tablet and one DHA capsule daily or as directed by a physician.

How Supplied

Gesticare DHA 30 count (6 Blister Cards) is supplied as six child-resistant blister cards containing 5 Gesticare delayed-release tablets and 5 DHA capsules each (NDC 18860-253-30).

Store at controlled room temperature 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F).

To report a serious adverse event or obtain product information, contact (800) 890-3098.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

Rx only

AZUR PHARMA

Distributed by: AZUR PHARMA, INC. • Philadelphia, PA 19103 • www.azurpharma.com
Manufactured by: Keata Pharma Inc. Markham, Ontario, Canada L3R 3T7
© 2009 Azur Pharma, Inc. 09/09 All rights reserved. GSTC DHA DR 09/001