

Duet®DHA Complete by StuartNatal®
Rx Only

DESCRIPTION: Duet® DHA Complete is a gluten free prescription regimen of prenatal multi-vitamin, multi-mineral, and omega-3 fatty acids, supplied as tablets and enteric-coated softgel capsules.

Each yellow oval Duet® Tablet* contains:

VITAMINS

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|---|----------|
| A (beta carotene) | 3,000 IU |
| C (ascorbic acid) | 120 mg |
| D (cholecalciferol) | 800 IU |
| E (dl-alpha tocopheryl acetate) | 3 mg |
| B ₁ (thiamine mononitrate) | 1.8 mg |
| B ₂ (riboflavin) | 4 mg |
| Niacinamide | 20 mg |
| B ₆ (pyridoxine hydrochloride) | 50 mg |
| Folic acid | 1 mg |
| B ₁₂ (cyanocobalamin) | 12 mcg |

MINERALS

| | |
|---|---------|
| Calcium (calcium carbonate) | 230 mg |
| Iron (polysaccharide iron complex and sodium iron EDTA, Ferrazone®) | 27 mg |
| Magnesium (magnesium oxide) | 25 mg |
| Zinc (zinc oxide) | 25 mg |
| Copper (cupric oxide) | 2 mg |
| Iodine | 220 mcg |

Each frosted golden-colored oval enteric-coated DHA Softgel Capsule* contains a clear solution of not less than 430 mg purified omega-3 long-chain fatty acids including DHA (docosahexaenoic acid), EPA (eicosapentaenoic acid) and DPA (docasapentaenoic acid) in approximately 628 mg of fish oil.

OMEGA-3 FATTY ACIDS

| | |
|---|---------------------|
| Total omega-3 long-chain fatty acids | No less than 430 mg |
| As DHA | No less than 295 mg |
| As other omega-3 long-chain fatty acids | No less than 135 mg |

OTHER INGREDIENTS (Duet® Tablet): Acacia, corn starch, croscarmellose sodium, D&C Yellow No. 10, dicalcium phosphate, dl-alpha tocopherol, FD&C Yellow No. 6, food starch, gelatin, glucose, hydroxypropyl methylcellulose, hypromellose, lecithin, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, silicon dioxide, sodium ascorbate, sodium benzoate, sorbic acid, sucrose, talc, triglycerides, titanium dioxide, xanthan gum.

OTHER INGREDIENTS (Enteric-coated DHA Softgel Capsule): Ammonium hydroxide, ethylcellulose, fractionated coconut oil, gelatin, glycerin, oleic acid, stearic acid, sodium alginate, and DHA and EPA concentrate derived from purified fish oil via a proprietary process.

***Compliance:** The yellow oval Duet® Tablet is formulated in conformance with official U.S. Pharmacopeia (USP) standards of quality for potency, purity and dissolution. Duet® Tablet, as manufactured, is subject to Quality Control Standards and Good Manufacturing Practices established by the U.S. FDA. The DHA concentrate complies with The Global Organization for EPA and DHA Omega-3s (GOED) Voluntary

Monograph for identity and purity. The DHA concentrate is also certified to meet Friend of the Sea Sustainable Fisheries criteria.

INDICATIONS: Duet® DHA Complete is a gluten free prescription regimen of prenatal multi-vitamin, multi-mineral, and omega-3 fatty acid supplements indicated for use in improving the nutritional status of women throughout pregnancy and in the post-natal period for both lactating and non-lactating mothers. Duet® DHA Complete is also useful in improving the nutritional status prior to conception.

CONTRAINDICATIONS: This product is contraindicated in patients with known hypersensitivity to any of the ingredients, including fish or fish oil.

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

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 a poison control center immediately.

Since daily ingestion of more than 3 grams per day of omega-3 fatty acids (including alpha-linolenic acid (ALA), eicosapentaenoic acid (EPA), and docosahexaenoic acid (DHA)) from fish oils may have potential antithrombotic activities and may increase bleeding times, administration of DHA should be avoided in patients with inherited or acquired bleeding diatheses, including those taking anticoagulants.

PRECAUTIONS: Folic acid in doses above 0.1 mg daily may obscure the diagnosis of pernicious anemia (hematologic remission may occur while neurological manifestations remain progressive).

DRUG INTERACTIONS: Pyridoxine supplements should be avoided in patients receiving levodopa alone, as the actions of levodopa may be antagonized.

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

DOSAGE AND ADMINISTRATION: Before, during and after pregnancy, one tablet and one enteric-coated softgel capsule taken by mouth daily, or as directed by a physician. The tablet and enteric-coated softgel capsule may be taken together or at different times of the day. Caution should be exercised to ensure that the prescribed dose of DHA does not exceed 1 gram (1,000 mg) per day.

HOW SUPPLIED: NDC 66479-890-30. Duet® DHA Complete is supplied in child-resistant blister cards containing 30 doses per carton (1 Duet® tablet and 1 enteric-coated DHA softgel capsule equals 1 daily dose). Each unit-of-use dispensing carton contains 5 cards with 6 unit-doses per card which is a 30-day supply. The yellow oval Duet® tablet is imprinted with the StuartNatal® logo (“heart-in-a-heart”) on one side and “885” on the other. The frosted golden-colored oval enteric-coated DHA softgel capsule is imprinted with the StuartNatal® logo (“heart-in-a-heart” outlined traced) on one side and X1 on the other.

STORAGE: Store at controlled room temperature 20-25°C (68-77°F). Protect from moisture and excessive heat. Note that contact with moisture may produce surface discoloration of the tablet.

DISPENSING: Keep in a well-closed, light-resistant container as defined by the USP. Unit dose blisters are child-resistant to opening as a safeguard against ingestion by children. KEEP THIS AND ALL MEDICATIONS OUT OF REACH OF CHILDREN.

To request medical information or to report suspected adverse reactions, contact Xanodyne Medical Affairs at 1-877-773-7793.

www.DuetDHA.com

Marketed by: 
Newport, KY 41071, USA

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PI-890-A Revision 08/2010