



# Quatrefolic® during pregnancy

National and international guidelines suggest a **400 mg/day** intake <sup>(5)</sup>

It is required to:

**REDUCE**  
THE RISK OF  
INBORN NEURAL  
TUBE DEFECTS

**REDUCE**  
THE RISK OF  
PRE-ECLAMPSIA



1 soft gel/day preferably with a meal

Average content	For 1 softgel
Total Omega-3	508 mg
DHA	450 mg
EPA	18 mg
Quatrefolic® (5 MTHF-glucosamina)	741 µg
Folate (corresponding to 741 mcg of 5 MTHF-glucosamine)	400 µg 200% NRV**

\*\*Nutrient Reference Values (NRVs)

1. **PRODUCT NAME:** VitaDHA® materna 450

2. **INGREDIENTS:** fish oil purified and concentrated in omega-3 fatty acids in triglyceride form (DHA Plus®); capsule shell: fish gelatine; emulsifier: mono and diglycerides of fatty acids, sunflower lecithin; stabilizer: vegetable glycerol; pur. water; coconut oil; colorant: titanium dioxide, iron oxide; Quatrefolic® ((6S)-5-Methyl-tetrahydrofolic acid (5MTHF-glucosamine), glucosamine salt); vanilla flavour.

3. **PHARMACEUTICAL FORM:** pack of 30 softgel capsules.

4. **PRODUCT INFORMATION**

4.1. **Product characteristics:** VitaDHA® materna 450 is a food supplement of high quality omega-3 docosahexaenoic acid (DHA Plus®) in a highly absorbable triglyceride form derived from fish oil purified through multiple molecular distillation and Quatrefolic® (5MTHF-glucosamine), source of folate. VitaDHA® Materna is particularly recommended in cases of reduced intake with food or increased need of its nutrients, especially when planning a pregnancy, during pregnancy and lactation.

4.2. **Components of the formulation:** Docosahexaenoic acid (DHA): DHA is a fundamental nutrient during pregnancy both for the mother and the foetus. DHA is the main omega-3 fatty acid contained in the nervous structures, it is selectively collected within the brain during the growth and expansion of the cerebral cortex in the perinatal period. DHA maternal intake contributes to the normal brain and visual development of the foetus and breastfed infants. The beneficial effect is obtained with a daily intake of 200 mg of DHA in addition to the recommended daily intake for omega-3 fatty acids DHA and EPA of 250 mg.

Quatrefolic®: is the active form of folic acid and it does not need any enzymatic activation to be absorbed and has been shown to have greater stability and bioavailability compared to the common form of acid folic. Supplemental folic acid intake increases maternal folate status. Low maternal folate status is a risk factor in the development of neural tube defects in the developing foetus. The beneficial effect is obtained with a supplemental folic acid daily intake of 400 µg for at least one month before and up to three months after conception. Folate contributes to maternal tissue growth during pregnancy. Folate contributes to normal homocysteine metabolism.

BIBLIOGRAFIA

- 1) Koletzko B. et al. World Ass. Perin. Med. Racc., J. Perinat. Med. 2008, 36(1): 5-14.
- 2) J. Dyerberg et al. 1995, Bioavailability of n-3 Fatty Acid Formulations In n-3 Fatty Acids: Prevention and Treatment in Vascular Disease
- 3) Olsen S.F. et al. BMJ 2002, 324: 447-449
- 4) Martinez M. J. Pediatr. 1992, 120(suppl): S129-S138.

Quatrefolic® is a registered trademark of Gnosis S.p.A. Food and Drug Administration has recognized Quatrefolic® as a New Dietary Ingredient (NDI) and as GRAS (Generally Recognized As Safe).

4.3. **Contraindications:** known hypersensitivity toward one of the product ingredients or other strictly related substances.

4.4. **Side effects:** symptoms of hypersensitivity such as belching, flatulence and diarrhea are very rare. Such symptoms generally occur when the recommended dosage is significantly exceeded (6-10 softgels) and readily disappear by reducing the dosage or temporarily suspending the assumption of the product.

4.5. **Warnings:** keep out of reach of children under the age of 3 years. Health supplements are not a substitute of a varied and a balanced diet and a healthy life style. Do not exceed the recommended dosage.

4.6. **Interactions:** none known.

4.7. **Effects on the ability to drive or operate machinery:** none known.

4.8. **Other warning:** due to the natural origin of components, different production batches may vary in color.

4.9. **Dosage and mode of administration:** the recommended dosage is 1 softgel daily before meal. Administration with meals improves absorption of the active nutrients.

5. **OTHER INFORMATION**

5.1. **Packaging:** carton box containing 2 PVDC blisters of 15 capsules each.

5.2. **Validity:** 36 months from the day of the production if properly stored. For the expiry date see side of the box.

5.3. **Storage:** store in a cool, dry place, away from direct heat, light and humidity sources.

6. **MARKETING AUTHORIZATION HOLDER**

6.1. **Marketing authorization and Licence holder:** U.G.A. Nutraceuticals S.r.l. unipersonale - Registered office: via L. Da Vinci, 129/C - 06024 Gubbio (PG) - Italy; Headquarter: via L. Pavoni, 1 - 20900 Monza (MB) - Italy.

6.2. **Manufacturer:** AYANDA GmbH & Co. KG, site address: Am Hunengrab 20, 16928 Pritzwalk Germany

- 5) Rapporto Istisan n. 13/28 - Prevenzione primaria delle malformazioni congenite: attivita del Network Italiano Promozione Acido Folico. ISS 2013
- 6) <http://www.quatrefolic.com/bioavailability.html>
- 7) Mills M.J. et al. The Lancet 1995, 345: 149-151
- 8) Leeda M. et al. Am. J. Obstet. Gynecol 1998, 179: 135-139



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HCP's use only



# DHA during pregnancy

DHA maternal intake contributes to the normal brain and visual development of the fetus and breastfed infants. The beneficial effect is obtained with a daily intake of **200 mg DHA** in addition to the recommended daily intake for omega-3 fatty acids DHA and EPA of 250 mg.

**VitaDHA Materna 450:**  
NEW FORMULA with 200 + 250 mg DHA

To:

**REDUCE**  
RISK OF PRETERM  
DELIVERY

**ENSURE**  
OPTIMAL FETUS CNS  
DEVELOPMENT

# vitaDHA® materna 450

Food supplement of  
omega-3 fatty acid **DHA PLUS™**  
and **Quatrefolic®**



the **BALANCE**  
of a **TWO**  
**PRONGED**  
**ACTION**

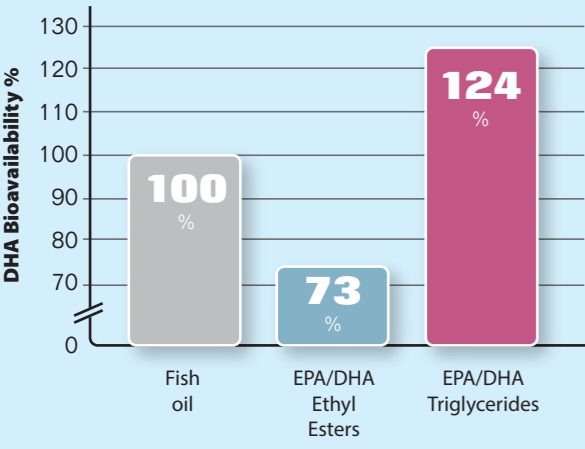


Fish  
Gelatin

**NEW FORMULA**



# DHA IN PERFECT BALANCE

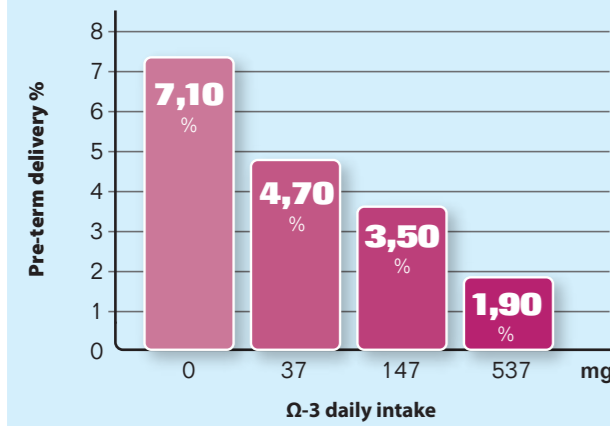
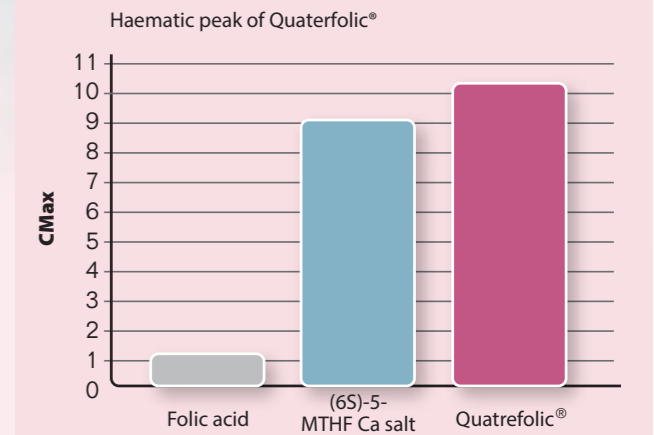


- 🕒 **A formulation purified** from metallic ions (mercury, lead, arsenic)
- 🕒 **Optimal bioavailability** <sup>(2)</sup>
- 🕒 **Better digestibility** thanks to its triglyceride form <sup>(2)</sup>

**HIGHER BIOAVAILABILITY**  
PURIFIED AND  
STANDARDIZED **DHA**  
IN TRIGLYCERIDE FORM

**HIGHEST BIOAVAILABILITY**  
**FOLIC ACID**  
IN ITS BIOLOGICALLY  
ACTIVE FORM

- 🕒 **Quatrefolic® doesn't need enzymatic activation to be absorbed** <sup>(6)</sup>

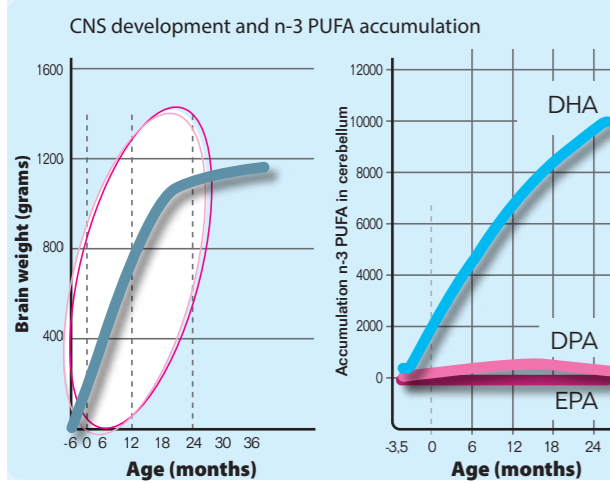
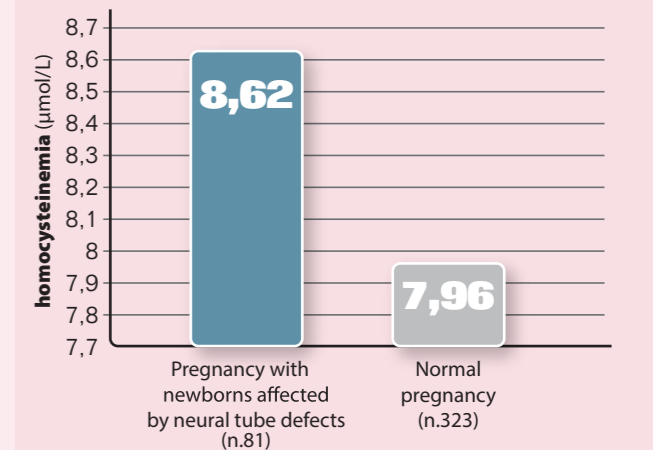


- 🕒 **Omega-3 reduces** in a dose dependent **manner** the **preterm delivery risk** up to **73%** <sup>(3)</sup>

**REDUCTION OF PRETERM DELIVERY INCIDENCE**

**REDUCES PLASMATIC HOMOCYSTEINE LEVELS**

- 🕒 The homocysteine metabolism disturbances are **wide spread** in women which deliver infants with **neural tube defects** <sup>(7)</sup>

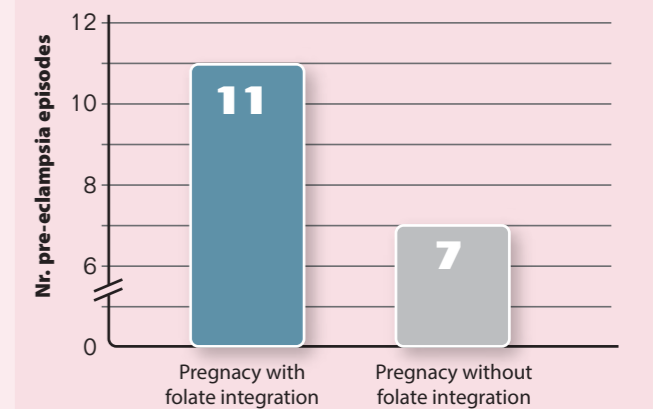


- 🕒 **CNS development** is directly related to **DHA accumulation** <sup>(4)</sup>

**FAVORS THE OPTIMAL CNS DEVELOPMENT**

**REDUCES THE RISK OF PRE-ECLAMPSIA**

- 🕒 The **hyper-homocysteinemia** is a **risk factor** in women with recurrent and **unexplainable abortions** <sup>(8)</sup>



\*\*741 µg di Quatrefolic® (5MTHF-glucosamina) corresponding to 400 µg of folate. Quatrefolic® is a registered trademark of Gnosis S.p.A.