

Omegaformula

FOOD SUPPLEMENT

NORMAL BLOOD CHOLESTEROL LEVELS

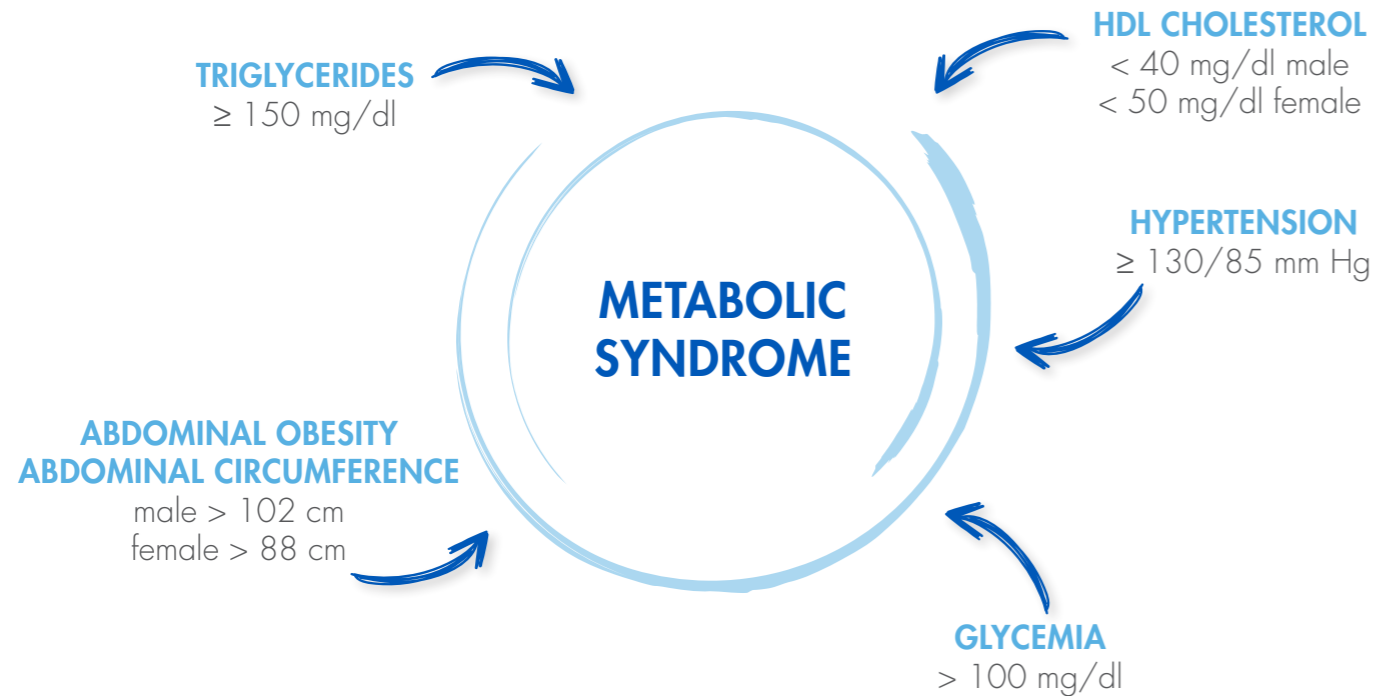
Why Omegaformula

Cardiovascular diseases are one of the most important causes of mortality, morbidity and disability in the world. These diseases have a multifactorial etiology depending on different predisposing conditions:

- age
- gender
- smoke addiction
- unbalanced diet
- sedentary lifestyle
- medicines intake
- overweight
- oxidative stress
- increased levels of homocysteine
- post-menopause

The concomitance of some of these predisposing conditions may bring about the onset of the so-called Metabolic Syndrome, a real "epidemic" of the third millennium.

The **Metabolic Syndrome** is diagnosed when at least 3 of the following risk factors are concomitant:



Omegaformula is a food supplement whose specific and synergistic formulation **helps maintaining normal blood cholesterol levels**¹⁻².

Omegaformula, combined with healthy dietary habits and lifestyle, helps to:

- keep a proper physiological LDH/HDL ratio¹⁻²
- keep proper physiological homocysteine levels. Increased homocysteine levels are one of the main causes of oxidative stress leading to atherogenic processes¹⁻².



Omegaformula - Ingredients

RED YEAST RICE

standardized to 1.5% Monacolin K

Balance of the physiological levels of:

- LDL cholesterol
- Triglycerides

MICRONIZED BAOBAB SEEDS

- Natural intake of poly unsaturated $\Omega 3$ $\Omega 6$ $\Omega 9$ fatty acids and vegetable fibre
- Contribute to the **regularity of the blood pressure**



VITAMIN B6 FOLIC ACID COCOA

- Contribute to the **physiological metabolism of homocysteine**
- Vitamin B6 contributes to **normal energy-yielding metabolism**
- Folic acid contributes to **normal blood formation**



- **RED YEAST RICE**³⁻⁴⁻⁵

It is obtained from the natural fermentation of rice (*Oryza sativa* L.) with a yeast, the *Monascus purpureus*, which produces special triterpenoids, such as **mevinolin** and **monacolin K**.

The latter is a natural inhibitor of **HMG CoA reductase (3-hydroxy-3-methylglutaryl-CoA reductase)**, responsible for the production of mevalonic acid, a key reaction for the endogenous cholesterol production process.

A DAILY INTAKE OF 10 MG OF MONACOLIN K FROM RED YEAST RICE HELPS MAINTAINING NORMAL BLOOD CHOLESTEROL LEVELS.

- **MICRONIZED SEEDS OF BAOBAB FRUIT**⁶

Thanks to a special pharmaceutical technique, the phyto-complexes of the fibre containing a naturally balanced ratio of **omega 3 – omega 6 – omega 9, and phytosterols** remain unaltered. Polyunsaturated fatty acids play a metabolic and structural key role. **ASSUMED TOGETHER HELP TO KEEP PHYSIOLOGICAL LEVELS OF LDL/HDL RATIO. Recent studies show that there is no connection between the intake of high levels of omega 3 and cholesterol decrease, whereas they confirm an increased risk of lipoprotein peroxidation of the cell membrane.**

The intake ratio of polyunsaturated omega 3 - omega 6 - omega 9 fatty acids is particularly significant, especially the **intake ratio of omega 6**, which is electively involved in the **REDUCTION OF LDL CHOLESTEROL.**



- **VITAMIN B₆**⁹

It is essential as cofactor in different metabolic processes. Vitamin B₆ deficiency affects the 30% of the elderly: this deficiency is associated with an increased cardiovascular risk, since it exerts an antiplatelet and preventative action against coronary heart disease. **THE DAILY DOSAGE OF OMEGAFORMULA PROVIDES OVER 200% OF THE AVERAGE DAILY NEED, THUS HELPING TO REDUCE CARDIOVASCULAR RISK.**

- **FOLIC ACID**¹⁰⁻¹¹

Another important factor associated with cardiovascular risk is an increased homocysteine level. This increase is, in fact, directly connected with an increased risk of endothelial injury in arteries, due to a decreased NO (nitric oxide) production, to an increased platelet aggregation and to LDL oxidation.

Recent studies show that the daily intake of folic acid through diet and food supplementation have preventative effects.

A DAILY DOSAGE OF OMEGAFORMULA PROVIDES 150% OF THE AVERAGE DAILY NEED OF FOLIC ACID.

- **COCOA**¹²

Thanks to its high amounts of polyphenols with antioxidant activity, Cocoa exerts a **PROTECTIVE ACTION ON THE CARDIOVASCULAR SYSTEM.**

Overview on pharmacological and nutraceutical strategies for treatment of borderline dyslipidemia

Andrea Lozzi – *Minerva Cardioangiologica* 2014, vol 62 - n.3 - pag 1-6

Cardiovascular system pathologies are responsible for 30-35% of deaths in industrialized countries, making cardiovascular pathology the leading cause of disease-induced death. The substrate for the development of cardiovascular disease is represented by many risk factors and the presence of a chronic inflammatory state. Hypercholesterolemia is considered one of the most important risk factors and, consequently, a primary therapeutic target. Numerous therapeutic strategies, based mainly on the use of statins, have been developed for hypercholesterolemia management. Unfortunately, those established drug therapies may present low effectiveness and low compliance by the patients.

In this overview we discuss the results of a cohort observational prospective clinical trial with active control which aims to evaluate the **effectiveness of the experimental treatment with Omegaformula** compared to conventional treatment with Atorvastatin.

Study design: The study was conducted in Italy on 30 subjects aged over 18 years enrolled according to defined criteria, divided into two homogeneous groups and treated for 3 consecutive months with 10 mg/day of Atorvastatin (control group - GC) or 3 tablets/day of **Omegaformula** (experimental group - GS) and followed up with evaluation of biophysical and haematic parameters.

Results: at the end of the treatment, the result of reduction of total cholesterol plasmatic levels (primary endpoint) in the group of subjects treated with **Omegaformula** (GS Group) has been reached (-17.82%); the reduction of total cholesterol in the group treated with Atorvastatin (GC Group) was instead of -14.25% - *Table 1*.

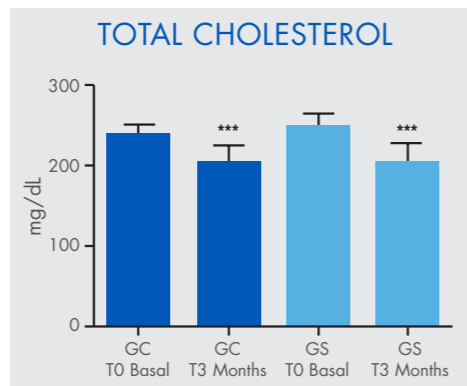


Table 1

The set of data on the secondary endpoints shows a framework of substantial equivalence between treatment with Atorvastatin (GC Group) and with **Omegaformula** (GS Group).

Parameters (A) LDL / HDL ratio (-28.41%) and (C) circulating homocysteine (-20.17%) show the efficacy of **Omegaformula** in modulating these values. Treatment with Atorvastatin proves to be beneficial in managing the levels of triglycerides (-18.83%) (B) - *Table 2*.

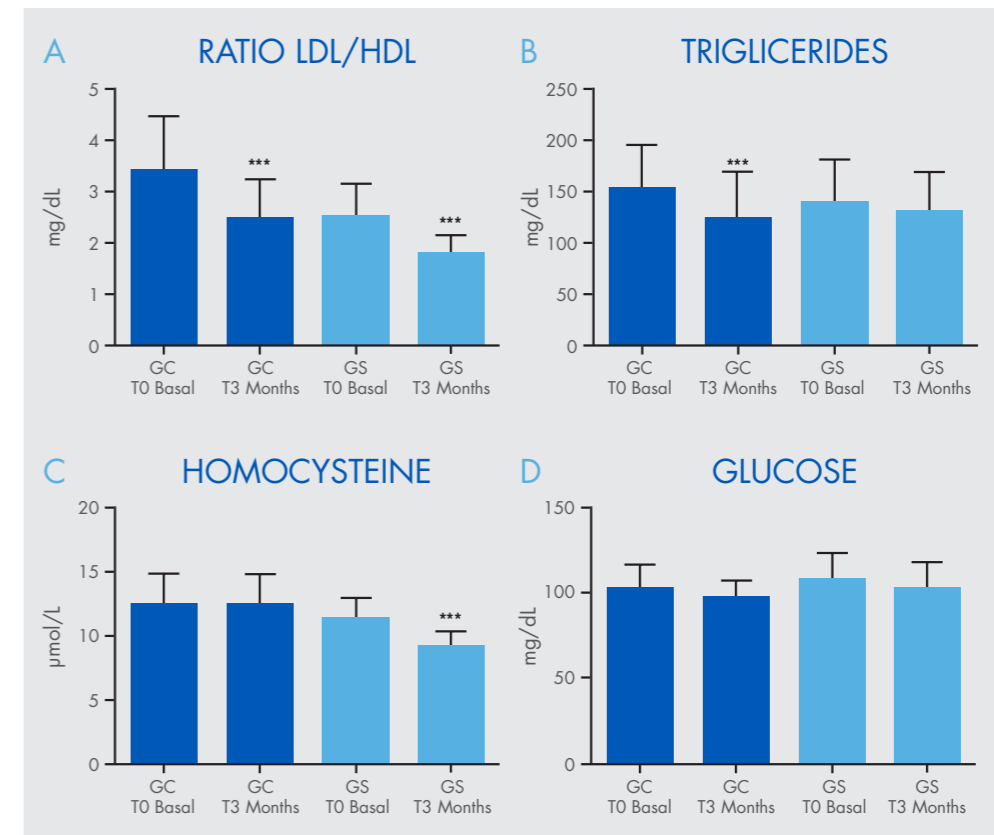


Table 2

Conclusions: the evaluation of the effectiveness of the tested treatment, consisting in the assumption of **Omegaformula** compared with the assumption of Atorvastatin for a total period of three months, shows the equivalence between the two treatments in reducing hyperlipidemia.

Omegaformula - The plus

Formulated with ingredients that act synergically to help **keep normal blood cholesterol levels**

With MICRONIZED BAOBAB seeds that contribute to the regularity of the blood pressure

Intake of highly biocompatible and gastroprotective **phytocomplexes and fibre associated with polyunsaturated fatty acids**

Good daily intake of **Vitamin B6 and Folic acid to control normal homocysteine metabolism**

Easy to use, **cocoa flavoured chewable tablets**

Omegaformula

Nutritional support recommended in cases of:

- tendency to hypercholesterolemia and hypertriglyceridemia
- metabolic syndrome and cardiovascular risk
- contraindications due to the use of lipid lowering or cholesterol lowering drugs



Omegaformula - Suggested combinations

Omegaformula + Gunabasic

Acid-base balance and maintenance of normal blood cholesterol levels.



Gunabasic

15 x 7 g sachets -
Net weight 105 g
with sweetener

Omegaformula + Epatoguna

Physiological maintenance of liver function and maintenance of normal blood cholesterol levels.



Epatoguna

32 x 1,125 g tablets
Net weight: 36 g

Omegaformula + Gunaminoformula

Metabolic Syndrome.



Gunaminoformula

- 24 x 6.5 g sachets
Net weight 156 g
with sweetener
- 50 x 1.01 g tablets
Net weight 50.5 g

Omegaformula + Profemplus

Regulation of cholesterol levels in menopausal syndrome.



Profemplus

20 x 4.8 g sachets
Net weight 96 g
with sweeteners

Nutrition Facts

| | per 100 g | per 3 tablets | %NRV* per 3 tablets |
|--|---------------------|-----------------------|------------------------|
| Energy | 1320 kJ 316 kcal | 79 kJ 19 kcal | |
| Fat of which saturates | 8.27 g 3.34 g | 0.50 g 0.20 g | |
| Carbohydrate of which sugars | 65.83 g 1.97 g | 3.95 g 0.12 g | |
| Proteins | 9.81 g | 0.59 g | |
| Salt | 0.30 g | 0.02 g | |
| Baobab (seed) of which: | 25 g | 1500 mg | |
| Omega 3 | 0.09 g | 5.40 mg | |
| Omega 6 | 1.49 g | 89.25 mg | |
| Omega 9 | 1.43 g | 85.95 mg | |
| polyphenols | 0.03 g | 1.50 mg | |
| free sterols | 0.09 g | 5.10 mg | |
| Red yeast rice of which Monacolin K | 11.11 g 0.17 g | 666.66 mg 10.00 mg | |
| Vitamine B6 | 50 mg | 3.00 mg | 214 |
| Folate | 5000 µg | 300 µg | 150 |

*NRV: Nutrient Reference Values

Packaging

80 x 2 g chewable tablets - Net weight 160 g e

Instuction for use

3 chewable tablets per day are recommended. Take one chewable tablet during or after each main meal. Tablets must be chewed.

The information herein contained concern the ingredients of **Omegaformula** and should not be interpreted as medical advice, nor can they replace any medical prescription. Food supplements are not intended as means for treating, preventing, diagnosing or mitigating any disease or abnormal condition.

Ingredients

Sweetener: sorbitol (from maize or **wheat**); Baobab (*Adansonia digitata* L.) micronized seed, red yeast rice (*Monascus purpureus*) powder - 1.5% monacolin K, maltodextrin, unsweetened cocoa powder, flavouring, anti-caking agents: silicon dioxide, sodium carboxy methyl cellulose, cellulose gum, vegetable magnesium stearate; sweetener: sucralose; pyridoxine hydrochloride (vitamin B6), pteroylmonoglutamic acid (folate).

- with sweeteners -



Warnings

Store the product in a cool and dry place and protect from light. The expiry date refers to a product correctly stored in its original and undamaged packaging. Do not exceed the stated recommended daily dose. Keep out of the reach of young children. Excessive consumption may produce laxative effects. Before using the product please seek medical advice. Do not take during pregnancy, breast-feeding, or in case of treatment with lipid-lowering drugs. Food supplements should not be used as a substitute for a varied diet and a healthy lifestyle.

References

- Lozzi A. "Trattamento delle dislipidemie e della low-grade chronic inflammation vasale con Omega Formula™". *Advanced Therapies*. 2014, anno III - n.4.
- Lozzi A. "Overview sulle strategie di trattamento farmacologico e nutraceutico della dislipidemia border-line". *Minerva Cardioangiologica* 2014, vol 62 - n.3 - pag 1-6.
- Halbert S.C. et Al. "Tolerability of red yeast rice versus pravastatin in patients with previous statin intolerance". *Am J Cardiol*. 2010 Jan 15;105(2):198-204.
- Becker D.J. et Al. "Red yeast rice for dyslipidemia in statin-intolerant patients: a randomized trial". *Ann Intern Med*. 2009 Jun 16;150(12):830-9, W147-9.
- Klimek M. et Al. "Safety and Efficacy of Red Yeast Rice (*Monascus purpureus*) as an alternative therapy for hyperlipidemia". *P T*. 2009 Jun;34(6):313-27.
- Williams J.T. et Al. "Baobab Monography". *The International Centre for Underutilised Crops (ICUC)*, 2002.
- Cestaro B. et Al. "Age- and dose-dependent effects of an eicosapentaenoic acid-rich oil on cardiovascular risk factors in healthy male subjects". *Atherosclerosis*. 2007 Jul;193(1):159-67.
- Harris W.S. et Al. "Omega 6 fatty acids and risk for cardiovascular disease: a science advisory from the American Heart Association Nutrition Subcommittee of the Council on Nutrition, Physical Activity, and Metabolism; Council on Cardiovascular Nursing; and Council on Epide". *Circulation* 2009; 119: 902-7.
- De Magistris R., Ciaramella B. "Nutrienti e Malattie Cronico-Degenerative". *Guna Editore*.
- Coppola A. et Al. "Omocisteina, folati e patologia tromboembolica". *la Rivista Italiana di Ostetricia e Ginecologia - Vol 1*. pag 13/19.
- Leo D. et Al. "Lowdose folic acid supplementation reduces plasma levels of the cardiovascular risk factor homocysteine in postmenopausal women". *Am J Obstet Gynecol* 183:945-947, 2000.
- Almoosawi S. et Al. "The effect of polyphenol-rich dark chocolate on fasting capillary whole blood glucose, total cholesterol, blood pressure and glucocorticoids in healthy overweight and obese subjects". *Br J Nutr*. 2009 Oct 13:1-9.





GUNA S.p.a.
Via Palmanova, 71 - 20132
Milan - Italy
export@guna.it