niacin capable of improving the level of plasmatic cholesterol by decreasing the level of LDL-cholesterol, by increasing the level of HDL and by interfering with the activity of the HMG-CoA enzyme involved in the synthesis of the cholesterol itself. US2012/0270849 describes a composition containing niacin or derivatives thereof, Omega-3 fatty acids, and phytosterols effective in the adjustment of the levels of both HDL and LDL cholesterol and of triglycerides.

IT1347883 shows a composition of nutraceutics comprising fermented red rice, niacin and polycosanols capable of reducing the level of total cholesterol up to a value of 24%. In particular IT1347883 describes compositions including for each single dose: a) dry extract of Monascus purpureus between 400 and 600 mg equal to a content of mevinolin between 1.2 and 2.4 mg, b) polycosanols from sugar cane wax between 2 and 2.8 mg with a content in octacosanol between 0.6 and 2.0 mg, c) niacin between 9 and 15 mg. In the described compositions it is also provided the presence of other components as coadiuvants and stimulants of the methabolism such as vitamin E, the folic acid, vitamin B6 and vitamin B12.

Although the dietetic compositions based upon natural nutrients are capable of obtaining encouraging results against a substantial absence of unwished side effects, the effectiveness of these compositions, however, still results to be far from that of the conventional drugs.

SUMMARY OF THE INVENTION

The present invention is directed to a composition of natural nutrients comprising for each unit dosage, to be administered preferably once a day, an effective amount of:
a fermented rice by means of a yeast selected among the red yeasts of rice (rice red yeast), polycosanols, niacin, sterols or stanols and suitable excipients.

The subject of the present application are then compositions as described in claims 1 to 16.

In one aspect, there is provided a composition comprising per dosage unit:

- rice rice red yeast having a titre in mevinolin comprised between 0.05 and 5% by weight;
- polycosanols;

- niacin;
- from 500 to 1000 mg, preferably from 600 to 900 mg, from sterols and/or stanols

at least one pharmaceutically acceptable excipient.

In one aspect, there is provided the use of the composition as described herein in the manufacture of a medicament for the treatment or prophylaxis of dyslipidemia.

In one aspect, there is provided a kit of parts containing separately one from the other one the components of the compositions as described herein, for simultaneous or consecutive administration.

The composition according to the present invention has shown an unexpected increase in the antidyslipidemic activity, higher than what expected based upon the activity performed by each component, without causing any unwished side effect.

Therefore a second subject of the present application are said compositions to be

following formula: rice rice red yeast168 mg, polycosanols 10 mg, niacin 27 mg, sterols 890 mg, glycerol 6000 mg, sorbitol 600 mg, carrot and hibiscus juice and dehydrated pulp 120 mg, acacia gum 40 mg, xanthan gum 40 mg, ascorbic acid 35 mg, sodium benzoate plus potassium sorbate 38 mg, sucrose esters of fatty acids 12 mg, sucralose 3 mg, water as needed to 15 g.

16. The composition according to claim 13, in the form of chewable tablet, having the following formula: rice red yeast 167 mg, polycosanols 10 mg, niacin 32 mg, sterols 800 mg, mannitol 460 mg, sucralose 5 mg, neohesperidin 1 mg, syrup of glucose 466 mg, vegetable stearin 60mg, citric acid 50mg, flavors13 mg, silicon dioxide 20 mg, magnesium stearate 16 mg.

17. Use of the composition according to any one of the preceding claims in the manufacture of a medicament for the treatment or prophylaxis of dyslipidemia.

18. The use according to claim 17, wherein the medicament comprises from 500 to 2000 mg/die sterols/stanols, and wherein the medicament is to be administered daily.

19. The use according to claim 17, wherein the medicament comprises from 500 to *1000 mg/die sterols/stanols, and wherein the medicament is to be administered daily.*

20. Kit of parts containing separately one from the other one the components of the compositions according to anyone of claims 1 to 12, for simultaneous or consecutive administration.