liver, which is the organ responsible for the metabolism of the various involved molecules.

In a not negligible percentage of the pharmacologically treated patients, in fact, an alteration appears in the enzymes correlated to the liver and myocardium metabolism, such as for example the so-called transaminases (glutamic oxaloacetic transaminase or GOT or the glutamic-pyruvic transaminase or GPT) or in the enzymes involved in the operation of the skeletal muscle tissue such as for example creatine phosphokinase (CPK).

In addition to this, the pharmacological treatments have rather high costs both for the patient and for the health system.

In order to avoid the drawbacks of the pharmacological treatments, alternative routes for the treatment of dyslipidemia have then been studied and scientifically evaluated, mainly based upon dietetic compositions and food supplements based upon natural nutrients.

Several natural compounds, known for a long time for their antidyslipidemic action, have been clinically evaluated by determining, when possible, the probable mechanism implied by such activity. Among these substances we mention: niacin which inhibits the oxydation of LDL-cholesterol and reduces the lipoprotein with low density and the triglycerides; red rice yeast, a product obtained from fermentation of rice thanks to a yeast *(Monascus ruber* or *Monascus purpureus)* containing, apart from sterols, isoflavones and other compounds, monacolin K, a statin inhibiting the cholesterol synthesis via HMG-CoA reductase; the long chain linear aliphatic alcohols such as for example the polycosanols commonly extracted from the sugar cane; the sterols of vegetable origin or phytosterols and the corresponding saturated derivatives, stanols, reducing the absorption of cholesterol at intestinal level (exogenous cholesterol); some mono-unsaturated fatty acids contained in olives, olive oil and in fruits with shell reducing the level of LDL and triglycerides; soya bean which shows a moderate reduction in the levels of total cholesterol, of triglycerides and of LDL; the green tea and the extracts thereof containing catechins which reduce the absorption of cholesterol at intestinal level and the levels of triglycerides; the fatty acids of the

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

The present disclosure 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:

- red rice 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 disclosure 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

used in the treatment or prophylaxis of dyslipidemias.

Furthermore with the amounts of sterols/stanols used by us it has been possible, with the other active principles and the suitable excipients, implementing pharmaceutically stable compositions, suitable to an industrial manufacturing, and suitable to an acceptable administration.

DETAILED DESCRIPTION OF THE INVENTION

The composition implemented according to the present invention has been surprisingly capable of obtaining an unexpected increased in the antidyslipidemic activity without inducing any undesired side effect, such as for example metabolic or enzymatic alterations on the organism, by using at the same time some ingredients with antidyslipidemic action in lower amounts than those generally provided in dietetic compositions of the known art.

What said has been possible above all by dosing the used amount of sterols/stanols.

The use of 1-3 g/day of stanols/sterols as generally recommended can involve a bad absorption of vitamin and of carotenoids in general. Moreover, the use of large amounts of liposoluble compounds, such as indeed sterols/stanols to be mixed with the other components of the composition, can constitute a problem not easy to be solved as far as the manufacturing of a pharmaceutical composition suitable to the patient's expectations is concerned. Surprisingly it has now been found that by using an amount of stanols/sterols between 0.5 and 1g for single daily dose, in association to the other components of the composition, it is possible keeping a reduction in the levels of LDL-cholesterol not lower to what would be obtainable with analogous use of sterols/stanols in the generally recommended amounts. We have had then evident indications that a reduced dosage of sterols/stanols, when associated to the other components of the composition, does not cause the predictable effectiveness reduction in decreasing the levels of LDL-cholesterol with respect to the dosages of sterols/stanols generally recommended when analogously associated to the same components.

The use of the compositions according to the present invention in subjects with hypocholesterolaemia in fact has involved a reduction in the levels of total cholesterol

up to 27% already after 2 months as from the treatment beginning.

The composition of the invention, then, can be used in a particularly advantageous and preferred way in the treatment or prophylaxis of dyslipidemias. In particular the above-mentioned composition allows using a lower amount of vegetable sterols than that indicated as effective in the recent guidelines (US Third Report of the National Cholesterol Education Program on Detection Evaluation and Treatment of High Blood Cholesterol in Adults) (Adult treatment panel III) and those issued by the American Heart Association.

More in particular, it has been found that the above-mentioned association of ingredients shows an unexpected synergic effect and it is able to obtain a high reduction in the cholesterol level even with lower dosages of sterols than those generally recommended in the state of art.

Therefore, the compositions of the invention are administered according to a dosage regime providing daily administrations of sterols/stanols from 500 to 2000 mg/day, preferably from 500 to 1000 mg/day, for example about 800 mg/day.

In some cases, the treatment can provide an initial phase with daily administrations of sterols/stanols from 500 to 2000 mg/day followed by a maintenance phase with daily administrations from 500 to 1000 mg/day.

According to the pathology gravity, the treatment can be continued for a period from 2 to 12 months, or from 1 to 5 years or in chronic form for the whole life.

The compositions of the invention include, per dosage unit, apart from at least one pharmaceutically acceptable excipient, the four components in the following independent amounts.

- 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

or

- red rice yeast having a titre in mevinolin comprised between 0.05 and 5% by weight;
- polycosanols;
- from 4 to 100 mg, preferably from 10 to 50 mg of niacin; and
- sterols and/or stanols

or

- red rice yeast having a titre in mevinolin comprised between 0.05 and 5% by weight;
- from 1 to 50 mg, preferably from 5 to 20 mg, of polycosanols;
- niacin; and
- sterols and/or stanols

or

- from 50 to 600 mg, preferably from 100 to 300 mg, of red rice yeast having a titre in mevinolin comprised between 0.05 and 5% by weight;
- polycosanols;
- niacin; and
- sterols and/or stanols

Within the present invention, it has also been found that it is possible obtaining an antidyslipidemic effect with particular effectiveness when the various ingredients of the composition are present in specific ponderal relationships one with respect to the other one. Generally, for the objects of the invention, the composition comprises for each unit dosage:

- from 50 to 600 mg of dry extract of a rice ferment thanks to a yeast selected among the red rice yeast, said extract having a titre in mevinolin comprised between 0.05 and 5% by weight;
- from 1 to 50 mg of polycosanols;
- from 4 to 100 mg of niacin; and
- from 500 to 1000 mg from sterols and/or stanols
- at least one pharmaceutically acceptable excipient

In this way, it has resulted to be possible introducing the needed amounts of active ingredients from the point of view of a reduction in the dyslipidemias by obtaining the above-mentioned unexpected and advantageous synergic effect.

A preferred embodiment of the present invention is constituted by a composition including:

- from 100 to 300 mg of dry extract of a rice ferment thanks to a yeast selected among the red rice yeast, said extract having a titre in mevinolin comprised between 0.05 and 5% by weight
- from 5 to 20 mg of polycosanols;
- from 10 to 50 mg of niacin; and
- from 600 to 900 mg from sterols and/or stanols.
- at least one pharmaceutically acceptable excipient.

Examples of compositions according to the invention comprise, apart from a suitable excipient:

- 167 mg of dry extract of a rice ferment thanks to a red rice yeast
- 10 mg of polycosanols;
- 35 mg of niacin; and
- 800 mg from sterols and/or stanols.

or:

- 168 mg of dry extract of a rice ferment thanks to a red rice yeast;
- 10 mg of polycosanols;
- 27 mg of niacin; and
- 890 mg from sterols and/or stanols (with a titre of 90%).

or:

- 167 mg of dry extract of a rice ferment thanks to a red rice yeast;
- 10 mg of polycosanols;
- 32 mg of niacin; and
- 800 mg from sterols and/or stanols.

Moreover, in the composition there can be other vitamins selected among the group constituted by: folic acid and its derivatives, vitamin B6, vitamin B12 and vitamin E.

Red yeasts from rice

One of the ingredients with antidyslipidemic action of the composition of the invention

is constituted by a rice ferment by a yeast selected among the red rice yeasts.

Preferably, the rise ferment by a yeast is used in the composition of the invention in the form of dry extract available in commerce with various titres (or standards) in mevinolin (lovastatin or monakolin K). For the objects of the invention, the titre in mevinolin of the dry extract is comprised between 0.05 and 5% by weight and, preferably, between 1 and 4% by weight.

Preferably, the composition of the invention comprises for each daily dosed amount an amount of the above-mentioned rice ferment (as dry extract) so as to deliver a total amount of mevinolin comprised between 0.5 and 15 mg.

More preferably, the amount of said rice ferment is so as to deliver a total amount of mevinolin comprised between 1 and 10 mg and still more preferably comprised between 2 and 6 mg.

In such case, in fact, it has been found that the amount of active principle (mevinolin) introduced into the organism is such as to obtain the greatest effectiveness while achieving at the same time the above-mentioned surprisingly synergic effect when in combination with the remaining antidyslipidemic ingredients (aliphatic alcohol, niacin and phytosterols).

To this regard, it is further to be noted that in the composition of the invention the above active principle (mevinolin) is in the form of complex with oligosaccharides and other substances, which generally increase the bioavailability thereof by contributing to reduce drastically the side effects thereof. These side effects can be considered as substantially absent compared to the administration of the same isolated and purified active principle typical of the pharmacological-type treatments. Preferably, the yeast used in the rice fermentation for the purpose of the invention is a yeast belonging to the class *Ascomycota* order *Eurotiales,* genus *Basipetospora*, species *Monascus.* Still more preferably, such microrganism is a yeast *Monascus purpureus* or *Monascus ruber* and the obtainable dry extract of rice ferment generally can be found in commerce with titres (or standards) in mevinolin comprised between the above-mentioned values of 0.05 and 5% by weight.

For the purpose of the present invention such dry extract of rice ferment obtained by

a yeast is commonly defined as 'red rice yeast'.

Linear aliphatic alcohol

A second ingredient among the ones with antidyslipidemic action of the composition of the invention is constituted by a mixture of linear aliphatic alcohols having from 14 to 36 carbon atoms, otherwise known with the term of "polycosanols".

Preferably, the above-mentioned mixture of linear aliphatic alcohols has a titre in octacosanol, a linear alcohol having 28 carbon atoms, comprised between 20 and 80% by weight.

The above-mentioned mixture of linear aliphatic alcohols can be obtained from a series of natural sources, thereamong it is possible mentioning – for example – wheat germ wax, rice germ wax, carnauba wax (exudate of leaves of *Copernicia prunifera*), sugar cane wax, beeswax, avocado oil, alfaalfa, bamboo and apple wax. Depending upon the specific origin of the mixture of linear aliphatic alcohols, the titre in octacosanol preferably can be comprised between 14 and 22% in polycosanols from beeswax, between 50 and 60% in the supercritic extract of polycosanols from rice wax and between 50 and 80% in polycosanols from sugar cane wax.

Preferably, the above-mentioned mixture of linear aliphatic alcohols comprises, apart from octacosanol even tetracosanol (alcohol with 24 carbon atoms), exacosanol (alcohol with 26 carbon atoms), triacontanol (alcohol with 30 carbon atoms) and dotriacontanol (alcohol with 32 carbon atoms).

In an additional preferred embodiment the composition of the invention then comprises polycosanols consisting of a mixture of linear aliphatic alcohols having 24 to 32 carbon atoms.

Niacin

A third ingredient among the ones with antidyslipidemic action of the composition of the invention is constituted by niacin also known as vitamin B3 or nitotinic acid.

Within the present description and in the subsequent claims, under the term of niacin, one wants to designate both the nicotinic acid as such and the amide thereof, nicotinamide.

In an aspect of the present invention the composition of nutrients comprises for each

daily dosed amount an amount of niacin comprised between 4 and 100 mg. Preferably, the composition of the invention comprises for each daily dosed amount an amount of niacin comprised between 10 and 50 mg.

Sterols or stanols

A fourth ingredient among the ones of the composition of the invention is constituted by sterols or stanols. The vegetable sterols are steroid alkaloids differing from cholesterol in the structure of the side chain thereof, whereas the vegetable stanols are 5α-saturated derivatives of the corresponding sterols. The main sources of vegetable sterols are vegetable oils, seeds, cereals, fruits with shell and vegetable ones (beans, mais, black olives, cauliflowers, oranges). The most abundant phytosterols are sitosterol, campesterol and stigmasterol contributing respectively to 60%, 30% and 3% of the intake of sterols of vegetable origin. On the contrary, the amounts of vegetable stanols in nature are much lower (mainly sitostanol and campestanol). To the purpose of the present invention a usable commercial source of phytosterols is represented by talloil (sub-product of the Kraft process for the woodworking), the percentage composition thereof is the following one: Beta-sitosterol max 80%, sitosterol max 15%, campesterol max 10%, stigmasterol max 3%, brassicasterol max 3%, campestanol max 2%, other sterols max 3%.

The role that sterols and stanols have in contributing to the reduction in high levels of cholesterol in the blood is well documented. They inhibit the absorption of cholesterol at intestinal level, most probably by means of preventing the process of intraluminal solubilisation.

In a preferred embodiment, the composition of the invention comprises, for each daily dosed amount, an amount of sterols and/or stanols comprised between 500 and 1000 mg. Preferably, the composition of the invention comprises, for each daily dosed amount, an amount of sterols and/or stanols comprised between 600 and 900 mg.

In a particular embodiment and with the purpose of obtaining an effective coadjuvant and stimulation action of the organism metabolism in relation to the antidyslipidemic action of the active ingredients in such sense (red riceyeast, long chain linear aliphatic alcohols, niacin and sterols /stanols), the composition of the invention, further

be ingested immediately and it has optimum palatability.

An additional preferred embodiment of the invention is constituted by a composition in oral solid form of chewable tablet wherein, in addition to the above-mentioned active principles, excipients are used selected from i) lubricants selected in the group constituted by magnesium stearates, calcium and zinc, ii) glidants selected in the group constituted by silicon dioxide, starch and talcum, iii) edulcorants selected in the group constituted by mannitol, sucralose, neohesperidin and syrup of glucose iv) flavors v) hydrogenated vegetable fats such as vegetable stearin; preferably as lubricant the magnesium stearate can be used and as glidant the silicon dioxide.

All compositions implemented according to the present invention are suitable to the administration of a single dosage unit per day, but depending upon the patient's needs the administration of two or three dosage units per day is also possible.

Additional features and advantages of the invention will result more from the following description of some not limitative examples of dietetic compositions according to the invention.

EXAMPLE 1

Oral composition in form of tablets

Formulation of each single dosage unit:

Red rice yeast *	167 mg
Polycosanols**	10 mg
Niacin	35 mg
Sterols	800 mg
Microcrystalline cellulose	270 mg
Magnesium stearate	9 mg
Silicon dioxide	9 mg
Total	1300 mg

* titre in mevinolin: 3% by weight

** polycosanols from sugar cane wax having titre in octacosanol around 60% (between 58 and 62%).

Preparation process: the single components of the formulation are weighed in the suitable amounts and mixed in a mixer until a perfect homogenization. The so-obtained mixture is introduced in suitable compressing apparatus to obtain, by direct compression, tablets with required weight and hardness.

EXAMPLE 2

Composition in form of liquid suspension

Formulation of each single dosage unit:

Red rice yeast *	168 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
Aroma Lampone	30 mg
Sodium benzoate + potassium sorbate (preservatives)	38 mg (18 + 20 mg)
Sucrose esters of fatty acids (emulsifying agent)	12 mg
Sucralose (sweeteners)	3 mg
Water	as required to 15000 mg
Total	15000 mg

* titre in mevinolin: 3% by weight

** polycosanols from sugar cane wax having titre in octacosanol around 60%

(betweem 58 and 62%).

*** concentrate of hydrodispersible phytosterols containing 90% of sterols, deriving from talloil

Preparation process: the single components of the formulation, both solids and liquids, are weighed in the suitable amounts and mixed in a mixer until a perfect homogenization of the resulting suspension in aqueous phase. The so-obtained suspension, after suitable physical checks of the half-finished product, is poured into a container for food use and from this one packed in single-dose stick pack. Once made the suitable quality checks, one proceeds with the packaging in the final cases.

The so-obtained composition is stable at room temperature (it does not need preservation at low temperature), it can be ingested immediately and it has optimum palatability.

EXAMPLE 3

Composition in form of chewable tablet

Formulation of each single dosage unit:

Red riceyeast *	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	50 mg
Flavors	13 mg
Silicon dioxide	20 mg

Magnesium stearate	16 mg
Total	2100 mg

* titre in mevinolin: 3% by weight

** polycosanols from sugar cane wax having titre in octacosanol of 60%.

Preparation process: the single active principles composing the formulation (red rice yeast, polycosanols, niacin and sterols) are weighed in the suitable amounts and mixed with silicon dioxide and magnesium stearate in a mixer until a perfect homogenization. The so-obtained mixture is pre-compressed and granulated. The granules are sieved and passed in a rotating mixer. To the granules, kept under vigorous stirring, the vegetable stearin is added at a temperature of 70°C until a complete covering of the granules. The mass temperature is kept around 45°C during the whole covering process. The edulcorants, the citric acid and the flavors are pre-mixed separately and added to the covered granules. The so-obtained mixture is introduced in suitable compressing apparatus in order to obtain, by direct compression, tablets with required weight and hardness.

EXAMPLE 4

Antidyslipidemic action

In order to verify in vivo the antidyslipidemic action consequent to the administration of the dietetic compositions of the invention, the following experimental protocol was used.

Each one of the compositions of the previous Examples 1-3 was tested on a group of patients affected by hypercholesterolemia. The test admission criterium was exclusively of ethical type, that is the subjects should not have pathologies correlated to the cardiovascular system, that is they should be in primary therapy.

The protocol provided a preparatory or "RUN-IN" phase wherein the subjects were subjected (when not already in this phase) to a period of at least 15 days of stabilization diet, wherein they should follow the general suggestions related to hygienic-alimentary healthy habits (no restrictive, nor typically hypocholesterolemizing diets). Once performed the checking haematochemical examinations, the subject then, before going to bed, took 2 tablets per day of the composition to be tested for the first

CLAIMS

1. A composition comprising per dosage unit:

- red rice 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.

2. The composition according to claim 1 comprising per dosage unit:

- red rice yeast having a titre in mevinolin comprised between 0.05 and 5% by weight;
- polycosanols;
- from 4 to 100 mg, preferably from 10 to 50 mg of niacin; and
- sterols and/or stanols

at least one pharmaceutically acceptable excipient.

3. The composition according to claims 1 or 2, comprising per dosage unit:

- red rice yeast having a titre in mevinolin comprised between 0.05 and 5% by weight;
- from 1 to 50 mg, preferably from 5 to 20 mg, of polycosanols;
- niacin; and
- sterols and/or stanols

at least one pharmaceutically acceptable excipient.

4. The composition according to anyone of claims 1 to 3, comprising per dosage unit:

- from 50 to 600 mg, preferably from 100 to 300 mg, of red rice yeast having a titre in mevinolin comprised between 0.05 and 5% by weight;
- polycosanols;
- niacin; and
- sterols and/or stanols

at least one pharmaceutically acceptable excipient.

5. The composition according to anyone of claims 1-4, comprising per dosage unit an amount of red rice yeast adapted to make a total quantity of mevinolin comprised between 0.5 and 15 mg.

6. The composition according to claim 5, wherein the amount of said red rice yeast is adapted to make a total quantity of mevinolin comprised between 1 and 10 mg.

7. The composition according to claim 5, wherein the amount of said red rice yeast is adapted to make a total quantity of mevinolin comprised between 2 and 6 mg.

8. The composition according to claims 1-7, wherein said red rice yeast is obtained with a yeast belonging to the class *Ascomycota,* order *Eurotiales*, genus *Basipeiospora,* species *Monascus.*

9. The composition according to anyone of claims 1-8, comprising polycosanols consisting of a mixture of linear aliphatic alcohols having from 14 to 36 carbon atoms, having a titre in octacosanol comprised between 50 and 80% by weight.

10. The composition according to claim 9 comprising polycosanols consisting of a mixture of linear aliphatic alcohols wherein, in addition to ocstacosanol, the tetracosanol, the hexacosanol, the triacontanol and the dotriacontanol are present.

11. The composition according to anyone of claims 1-10, further comprising for each unit dosage an effective amount of at least one ingredient selected from the group comprising: folic acid and its derivatives, Vitamin B6, vitamin B12 and vitamin E.

12. The composition according to anyone of the preceding claims, further comprising for each unit dosage at least one dietary acceptable excipient.

13. The composition according to anyone of the preceding claims, in solid or liquid form, selected in the group consisting of: capsules, soft capsules, microcapsules, tablets, chewable tablets, pearls, soluble powder, granulate, syrup, gel, solution, emulsion, suspension or dispersion or oral drops, even in form of bag, sachet or single-dose stick pack.

14. The composition according to claim 13, in the form of tablet, having the following formula: red rice yeast 167 mg, polycosanols 10 mg, niacin 35 mg, sterols 800 mg, microcrystalline cellulose 270 mg, magnesium stearate 9 mg, silicon dioxide 9 mg.

15. The composition according to claim 13, in the form of liquid suspension, having the

following formula: red rice yeast 168 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: red rice 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 60 mg, citric acid 50 mg, flavors 13 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/day 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/day 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.