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(54) Titre : COMPOSITION ORODISPERSIBLE COMPRENANT DES ACIDES GRAS POLYINSATURES ET NE PRESENTANT NI ODEUR NI GOUT DESAGREABLE

(54) Title: ORODISPERSIBLE COMPOSITION COMPRISING POLYUNSATURATED FATTY ACIDS WITHOUT BAD ODOUR OR TASTE

(57) Abrégé/Abstract:
The present invention relates to an orodispersible composition without bad odour, smell or taste comprising polyunsaturated fatty acids (PUFA), its process for preparation and its use as nutritional supplement or as dietary supplement for balancing the blood lipid level, preventing or reducing the risk of the development of atherosclerotic changes, disorders or diseases.

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(54) Title: ORODISPERSIBLE COMPOSITION COMPRISING POLYUNSATURATED FATTY ACIDS WITHOUT BAD ODOUR OR TASTE

(57) Abstract: The present invention relates to an orodispersible composition without bad odour, smell or taste comprising polyunsaturated fatty acids (PUFA), its process for preparation and its use as nutritional supplement or as dietary supplement for balancing the blood lipid level, preventing or reducing the risk of the development of atherosclerotic changes, disorders or diseases.

Orodispersible composition comprising polyunsaturated fatty acids without bad odour or taste

The present invention relates to an orodispersible composition without bad odour, smell or taste comprising polyunsaturated fatty acids (PUFA), its process for preparation and its use as nutritional supplement or as dietary supplement for balancing the blood lipid level, preventing or reducing the risk of the development of atherosclerotic changes, disorders or diseases.

Polyunsaturated fatty acids (PUFA) are the active ingredients e.g. in fish oil and are responsible for significant low blood lipid levels and low incidence of hypertension which was shown in a epidemiological study with Inuits (M.H. Davidson, P. R. Liebson, Cardiovascular Reviews&Reports 1986, 7, 461-472). In particular the blood concentration of the low density lipoprotein cholesterol (LDL) is lowered and that of the high density lipoprotein cholesterol (HDL) is increased. Coronary heart disease (CHD) is the major cause of death in the western countries and high plasma cholesterol levels, more specifically the LDL/HDL ratio, is highly correlated with the risk of CHD (Willett and Sacks, N. Eng. J. Med. 1991, 121, 324).

The PUFA found in fish oil have carbon chains of 18, 20 or 22 atoms and can be classified in n-3 omega and n-6 omega fatty acids which are essential for the human body. In particular the omega-3 fatty acids eicosapentenoic acid (EPA) and docosahexenoic acid (DHA) are only found in fish and other marine life. Fish oil is therefore the most important food source for omega-3 fatty acids.

Standard nutritional supplement of PUFA is achieved by a daily administration of 500-1000 mg liquid fish oil. The fish oil is normally administered in capsules in order to prevent the fishy smell and odour. Nevertheless some people experience gastrointestinal upset of the fishy smell even hours after the fish oil is taken. The reason is that after decomposition of the galantine wall in the gastro-intestinal tract, the voluminous dosage of the fish oil is released as a macroscopic drop which interfere with the resorption of the fish oil. The problems of bad smell, odour and resorption can be solved in part by microdispersed fish oil preparations as pulverulent or aqueous matrix as described in EP 0 276 772. However, even the microdispersed fish oil granule or powder has a remaining fishy smell when pressed in simple tablets, so that flavours or antioxidants are needed to be added to the formulations.

The flavours are used to domineer over the fishy smell of the fish oil as described e.g. in JP 08092587 or JP 08228678. Taste masking is also achieved by adding milk products to the fish oil formulation as described e.g. in US 2003/0198728 or JP 2002-204656 or by coating or encapsulating the PUFA as described e.g. in WO 2004/016720 and WO 2005/029978.

The reason for the fishy smell of the fish oil is based on the oxidation of the unsaturated part of the PUFA. In order to prevent oxidation and to stabilize the PUFA antioxidants e.g. tocopherol can be added to the formulation as described e.g. in DE 20105126 or EP 1 155 620.

Surprisingly it is found that a bad or fishy smell of the composition according to the present invention can be avoided.

Subject of the present invention is an orodispersible composition comprising

i) a fish oil, a perilla oil or a polyunsaturated fatty acids (PUFA); and

ii) a disintegrant which is a solid dispersion comprising mannitol, xylitol, microcrystalline cellulose, crospovidone and dibasic calcium phosphate.

The oral composition according to the invention has not a fishy or bad smell, odour or taste.

According to the present invention polyunsaturated fatty acids (PUFA) include, but are not limited to, fish oil, perilla oil, omega-3 fatty acids, omega-6-fatty acids, arachidonic acid, linoleic acid, alpha-linoleic acid, dihomogammalinoleic acid, eicosapentenoic acid (EPA), docosahexenoic acid (DHA) and mixtures thereof. Preference is given to fish oil, omega-3 fatty acids, eicosapentenoic acid (EPA), docosahexenoic acid (DHA) and mixtures thereof. Most preferably fish oil containing eicosapentenoic acid (EPA) and docosahexenoic acid (DHA) is used.

In a preferred embodiment the composition according to the invention comprises PUFA, in particular fish oil powder or granulate, in an amount of 5 % to 70%, more preferable 40 % to 60 % by weight of the composition. The total amount of the PUFA, in particular fish oil powder or granulate, used in the composition is 100 mg - 1000 mg, preferably 400 mg - 900 mg.

In a most preferred embodiment the composition according to the invention comprises eicosapentenoic acid (EPA) in an amount of 0.5 % to 10 %, preferably 1.5 % to 4 % by weight of the composition or in an amount of 1 % to 20 %, preferably 3 % to 8 % by weight of the fish oil powder or granulate contained in the composition. The total amount of EPA in the composition is 10 mg – 100 mg, preferably 15 mg – 50 mg.

In a most preferred embodiment the composition according to the invention comprises docosahexenoic acid (DHA) in an amount of 0.5 % to 10 %, preferably 1 % to 4 % by weight of the composition or in an amount of 1 % to 20 %, preferably 2 % to 6 % by weight of the fish oil

powder or granulate contained in the composition. The total amount of DHA in the composition is 10 mg – 50 mg, preferably 15 mg – 30 mg.

The PUFA, in particular the fish oil containing eicosapentenoic acid (EPA) and docosahexenoic acid (DHA), is used preferably in a microdispersed form as a granulate or powder, in a pulverulent or aqueous matrix as described in EP 0 276 772. Preference is given to a fish oil granulate or powder.

In a preferred embodiment the pulverulant matrix of the fish oil powder or granulate comprises at least a homogenous protective colloid, a surfactant, optionally a diluent, stabilizer and further pharmaceutical excipients. In the case of the aqueous matrix the mentioned ingredients are used as an aqueous solution.

The protective colloids of the pulverulant matrix include but are not limited to polypeptides such as gelatine, casein, caseinate, polysaccharides such as starch, dextrin, pectin, Arabic gum, milk, milk powder, polyvinyl alcohols, polyvinylpyrrolidone, vinylpyrrolidone-vinylacetate-copolymers, acrylic acid- and methacrylic acid-copolymers with acrylic acid- or methacrylic acid esters, methyl cellulose, carboxymethyl cellulose, hydroxypropyl cellulose, alginates or mixtures thereof.

Diluents of the pulverulant matrix include but are not limited to sugar or sugar alcohols e.g. saccharose, lactose, invert sugar, sorbit, mannit or glycerine.

Stabilizers of the pulverulant matrix include but are not limited to tocopherol, t-butyl hydroxytoluol, t-butyl hydroxyanisol and ethoxyquine.

Surfactants of the pulverulant matrix include but are not limited to esters of long chain fatty acids and ascorbic acid, esters of mono- and diglycerin and fatty acids and oxethylated derivatives thereof, esters of mono fatty acid glycerides with acetic acid, citric acid, lactic acid, diacetyltartrate, salts of 2-(2'-stearoyllactyl) lactic acid, polyglycerine fatty acid esters, sorbitan fatty acid esters, porpylenglycol-fatty acid esters, ascorbylpalmitate and lecithin.

The pulverulant matrix comprises fish oil in the amount of 5 % to 70 %, preferably 50 % to 60 %, one or more surfactants in an amount of 1 % to 30 %, preferably 5 % to 15 %, a protective colloid in an amount of 5 % to 50 %, preferably 10 % to 40 %, a diluent in an amount of 0 % to 70 %, preferably 3 % to 35 %, by weight of the dry mass of the fish oil powder or granulate.

In a preferred embodiment the pulverulant matrix comprises the fish oil in small particles having an average particle size of less then 10 µm, more preferably less then 1 µm, most preferably less then 0.5 µm.

The fish oil powder or granulate can be prepared as described in EP 0 276 772.

According to the present invention the solid dispersion responsible for rapid disintegration comprises mannitol, xylitol, microcrystalline cellulose, crospovidone and dibasic calcium phosphate wherein microcrystalline cellulose, crospovidone and dibasic calcium phosphate are dispersed in the mixture of mannitol and xylitol. The solid dispersion according to the invention can be prepared as described in EP 1 523 974.

The amount of mannitol and xylitol in the solid dispersion is from 40 % to 90 %, preferably from 50 % to 80 %, more preferably from 60 % to 78 %, and most preferably from 62 % to 78 % by weight of the solid dispersion, and the amount of mannitol and xylitol in the total composition is from 18 % to 41 %, preferably from 23 % to 36 %, more preferably from 27 % to 35 % , and most preferably from 28 % to 35 % by weight of the total composition.

The ratio by weight of mannitol and xylitol is from (98 to 67) : (2 to 33), preferably from (98 to 87) : (2 to 13), more preferably from (97 to 87) : (3 to 13), and most preferably from (96 to 89) : (4 to 11).

The amount of dibasic calcium phosphate (which corresponds to calcium monohydrogen phosphate) in the solid dispersion is from 1 % to 30 %, preferably 2 % to 15 %, and more preferably 3 % to 8 % by weight of the solid dispersion, and the amount of dibasic calcium phosphate in the total composition is from 0.4 % to 13 %, preferably 1 % to 7 %, and more preferably 2 % to 4 % by weight of the total composition.

The amount of microcrystalline cellulose in the solid dispersion is from 8 % to 22 %, preferably from 10 % to 22 %, more preferably from 12 % to 21 % by weight of the solid dispersion, and the amount of microcrystalline cellulose in the total composition is from 3 % to 10 %, preferably from 4 % to 10 %, more preferably from 5 % to 9 % by weight of the total composition.

The amount of crospovidone in the solid dispersion is from 5 % to 15 %, preferably from 5 % to 14 %, more preferably from 6 % to 13 % by weight of the solid dispersion, and the amount of crospovidone in the total composition is from 2 % to 7 %, preferably from 2 % to 6 %, more preferably from 3 % to 6 % by weight of the total composition.

In a preferred embodiment D-mannitol is used in the solid dispersion.

The composition according to the invention can comprise further active ingredients such as vitamins and minerals. Vitamins include, but are not limited to, vitamin A, beta carotene, vitamin C (ascorbic acid), vitamin D3 (cholecalcipherol), vitamin E (tocopherol acetate), vitamin B1

(thiamine), vitamin B2 (riboflavin), nicotinamide, vitamin B5 (panthothenic acid), vitamin B6 (pyridoxine), folic acid, vitamin B12 (cyanocobalamin), vitamin K1, vitamin K2, especially menaquinone 7-10, and biotin. Minerals include, but are not limited to, iron salts, copper salts, calcium salts such as calcium carbonate, calcium phosphate, calcium glycerophosphate; magnesium salts such as magnesium phosphate, magnesium sulphate (dihydrate) or magnesium oxide; zinc salts such as zinc citrate; selenium salts such as sodium selenate; potassium iodide; manganese salts such as manganese sulphate; molybdate salts such as sodium molybdate; chromium salts such as chromium chloride; sodium chloride and potassium chloride.

The composition according to the present invention can be used as nutritional supplement or as dietary supplement for balancing the blood lipid level, preventing or reducing the risk of the development of atherosclerotic changes, disorders or diseases in a patient. The inventive composition can also be used as nutritional or as dietary supplement for developing and maintaining the cognitive functions connected with e.g. eyes, memory, language etc. or for alleviating and/or preventing blood vessel diseases, cardiovascular, cerebrovascular and nervous diseases such as e.g. hypertension, cardiac infarction, Alzheimer, Parkinson and depression, or for alleviating hormonal, immunologic disorders or obesity. Furthermore, it can be used as nutritional or dietary supplement to support treatments of diabetes, cancer and/or inflammatory affections. A patient, for the purpose of this invention, is a mammal, including a human. The use as a nutritional or dietary supplement is especially preferred for pregnant women, children and elderly persons.

A further aspect of the invention is a method for balancing the blood lipid level, preventing or reducing the risk of the development of atherosclerotic changes, disorders or diseases, for developing and maintaining the cognitive functions connected with e.g. eyes, memory, language etc., for alleviating and/or preventing blood vessel diseases, cardiovascular, cerebrovascular and nervous diseases such as e.g. hypertension, cardiac infarction, Alzheimer, Parkinson and depression, or for alleviating hormonal, immunologic disorders or obesity or for supporting treatments of diabetes, cancer and/or inflammatory affections by administering the inventive composition as nutritional supplement or as dietary supplement to a patient which is, for the purpose of this invention, a mammal, including a human, especially pregnant women, children and elderly persons.

The composition according to the invention is administered orally one or more, preferably up to three, more preferably up to two times per day. With each administration the number of dosage forms taken in at the same time should not exceed two.

Nevertheless, it may in some cases be advantageous to deviate from the amounts specified, depending on body weight, individual behaviour toward the active ingredient, type of preparation and time or interval over which the administration is effected. For instance, less than the aforementioned minimum amounts may be sufficient in some cases, while the upper limit specified has to be exceeded in other cases.

Ingredients of the oral dosage form are those which are accepted for pharmaceuticals and nutritional supplements and physiologically unobjectionable, for example: as fillers cellulose derivatives (e.g. microcrystalline cellulose), sugars (e.g. lactose), sugar alcohols (e.g. mannitol, sorbitol), inorganic fillers (e.g. calcium phosphates), binders (e.g. polyvinylpyrrolidone, gelatin, starch derivatives and cellulose derivatives), and all other excipients required to produce formulations of pharmaceuticals and nutritional supplements of the desired properties, e.g. lubricants (magnesium stearate), e.g. disintegrants (e.g. crosslinked polyvinylpyrrolidone, sodium carboxymethylcellulose), e.g. wetting agents (e.g. sodium lauryl sulphate), e.g. release-slowing agents (e.g. cellulose derivatives, polyacrylic acid derivatives), e.g. coloured pigments.

Excipients for pharmaceuticals and nutritional supplements familiar to the skilled person are also described for example in the following handbook: "Handbook of Pharmaceutical Excipients", Rowe R.C., Sheskey P.J. & Weller, P.J., American Pharmaceutical Association, Washington, 4th edition 2003.

The orodispersible tablet mentioned herein is produced by general standard processes. The solid dispersion is produced as described in EP 1 523 974. E.g. tablets can be produced by mixing and/or granulating the active ingredients together with the excipients (e.g. the whole solid dispersion part) to form a blend which is finally pressed to tablets. Optionally different blends containing different ingredients and excipients can be premixed and combined to a final blend which is then pressed to tablets.

Advantage of the composition of the present invention is that for the preparation of the composition a complex and expensive taste masking technology known in the prior art such as coating of tablets or granules, adding of antioxidants, or putting the PUFA into a capsule is not needed. The composition of the present invention can be prepared by simple and well-known standard procedures. Another well-known taste masking method is the addition of flavours in order to cover and mask the bad smell. This taste masking method is normally restricted to only a few applicable flavours which have to be selected in each case. However, flavouring ingredients are not needed for taste masking in the composition of the present invention.

Preference is given to an orodispersible composition which is not a coated tablet, coated granule, or capsule or which does not comprise an antioxidant or flavour or other taste masking substance.

Preference is given to a fast disintegrating orodispersible tablet, that means it disintegrates rapidly in the oral cavity. The disintegration time of the fast disintegrating orodispersible tablet is less equal than 100 sec., preferably less equal than 80 sec.

The composition according to the present invention shows a good and/or fast resorption of the PUFA after administration of the composition. Furthermore the composition facilitates a quick intake, optionally without water or drink.

The composition according to the invention shows an acceptable hardness and friability to be manufactured without affecting the beadlet integrity, i.e. no PUFA exudates from the tablet matrix.

Examples:

Example 1:

An orodispersible tablet consisting of:

- 500 mg of dry fish oil powder (omega-3, 18:12) including 23.5 mg of EPA and 16.5 mg of DHA
- 500 mg of F-melt type C

and optionally the following excipients:

- 15 mg of anhydrous citric acid
- 10 mg of Aspartam

F-melt type C is a commercially available disintegrant and consists of crospovidone, mannitol, xylitol, dibasic calcium phosphate and microcrystalline cellulose (Fuji, Chemical Industry Co., Ltd., Japan) and can be prepared as described in EP 1 523 974.

Example 2:

An orodispersible tablet consisting of:

- 890 mg of dry fish oil powder (omega-3, 18:12) including 41.83 mg of EPA and 29.37 mg of DHA
- 750 mg of F-melt type C

and optionally the following flavours and excipients:

- 25 mg of anhydrous citric acid
- 35 mg of Aspartam
- 5 mg of stearic acid
- 5 mg of iron oxide (red)

F-melt type C is a commercially available disintegrant and consists of crospovidone, mannitol, xylitol, dibasic calcium phosphate and microcrystalline cellulose (Fuji, Chemical Industry Co., Ltd., Japan) and can be prepared as described in EP 1 523 974.

Example 3:

An orodispersible tablet consisting of:

- 500 mg of dry fish oil powder (omega-3, 18:12) including 23.5 mg of EPA and 16.5 mg of DHA
- 500 mg of F-melt type C

and optionally the following flavours and excipients:

- 15 mg of anhydrous citric acid
- 50 mg of Lemon flavour
- 20 mg of honey flavour
- 10 mg of Aspartam

F-melt type C is a commercially available disintegrant and consists of crospovidone, mannitol, xylitol, dibasic calcium phosphate and microcrystalline cellulose (Fuji, Chemical Industry Co., Ltd., Japan) and can be prepared as described in EP 1 523 974.

Example 4:

An orodispersible tablet consisting of:

- 890 mg of dry fish oil powder (omega-3, 18:12) including 41.83 mg of EPA and 29.37 mg of DHA
- 750 mg of F-melt type C

and optionally the following flavours and excipients:

- 25 mg of anhydrous citric acid
- 50 mg of Lemon flavour
- 20 mg of honey flavour
- 30 mg of pineapple flavour
- 35 mg of Aspartam
- 5 mg of stearic acid
- 5 mg of iron oxide (red)

F-melt type C is a commercially available disintegrant and consists of crospovidone, mannitol, xylitol, dibasic calcium phosphate and microcrystalline cellulose (Fuji, Chemical Industry Co., Ltd., Japan) and can be prepared as described in EP 1 523 974.

Manufacturing process for orodispersible tablets

Direct compression process :

All ingredients are mixed together in a tumble mixer for 20 min. and optionally 5 min. before the end the lubricant, if any, (stearic acid) is added. The final blend is pressed into tablets with a rotary press.

Results:

Examples 1 and 2 do not show any bad or fishy taste or smell, in examples 3 and 4 only small amounts of flavour are added to improve the taste of the otherwise savourless tablet.

The disintegration time is 40 ± 5 sec. for example 1 and 3 and 60 ± 5 sec. for example 2 and 4.

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CLAIMS:

1. An orodispersible composition, comprising:

(i) a fish oil, a perilla oil or a polyunsaturated fatty acid (PUFA); and

(ii) a disintegrant which is a solid dispersion comprising mannitol, xylitol, microcrystalline cellulose, crospovidone and dibasic calcium phosphate.

2. The composition of claim 1, wherein the PUFA is an omega-3 fatty acid, an omega-6-fatty acid, arachidonic acid, linoleic acid, alpha-linoleic acid, dihomogammalinoleic acid, eicosapentenoic acid (EPA), docosahexenoic acid (DHA) or a mixture thereof.

3. The composition of claim 1, wherein the fish oil contains eicosapentenoic acid (EPA) and docosahexenoic acid (DHA).

4. The composition of any one of claims 1 to 3, wherein the fish oil is a fish oil powder or a granulate.

5. The composition of any one of claims 1 to 4, wherein the amount of the fish oil, perilla oil, or PUFA is from 5 % to 70 % by weight of the composition.

6. The composition of any one of claims 1 to 5, wherein, the amount of the fish oil, perilla oil, or PUFA in the composition is 100 mg - 1000 mg.

7. The composition of any one of claims 1 to 6, wherein, in the solid dispersion, the microcrystalline cellulose, the crospovidone and the dibasic calcium phosphate are dispersed in a mixture of the mannitol and the xylitol.

8. The composition of any one of claims 1 to 7, further comprising at least one mineral and/or vitamin.

9. The composition of any one of claims 1 to 8, which is a fast disintegrating orodispersible tablet having a disintegration time of less equal than 100 sec.

10. The composition of any one of claims 1 to 9, which is not a coated tablet, coated granule, or capsule.

11. The composition of any one of claims 1 to 10, which does not comprise any antioxidant, or flavour or other taste masking substance.

12. A process for manufacturing of the composition according to any of claims 1 to 11, comprising a step of mixing the components.

13. A use of the composition according to any one of claims 1 to 11, as a nutritional supplement or as dietary supplement.

14. A use of the composition according to any one of claims 1 to 11, for the preparation of a nutritional supplement or dietary supplement for: balancing blood lipid level; preventing or reducing the risk of the development of atherosclerotic changes, disorders or diseases; developing and maintaining cognitive functions; alleviating and/or preventing blood vessel, cardiovascular, cerebrovascular and nervous diseases; alleviating hormonal or immunologic disorders, or obesity; or supporting treatments of diabetes, cancer and/or inflammatory affections.

15. The composition according to any one of claims 1 to 11, for: balancing blood lipid level; preventing or reducing the risk of the development of atherosclerotic changes, disorders or diseases; developing and maintaining the cognitive functions; alleviating and/or preventing blood vessel, cardiovascular, cerebrovascular and nervous diseases; alleviating hormonal or immunologic disorders, or obesity; or supporting treatments of diabetes, cancer and/or inflammatory affections.