Claims

1. A modified-release composition comprising orlistat and acarbose, comprising individually distinct parts with different release patterns:

a) a first part, G1, comprising acarbose and one or more of: a hydrophobic polymer, a lipid and a wax, and G1 comprises from about 5 to about 70% w/w of the total dose of acarbose;

b) a second part, G2, comprising acarbose, orlistat, an enteric polymer and a surfactant, and G2 comprises from about 30 to about 95% w/w of the total dose of acarbose, and from about 10 to about 90% w/w of the total dose of orlistat;

and

c) a third part, G3, comprising orlistat and one or more of a surfactant and a water-soluble polymer, and G3 comprises from about 10 to about 80% w/w of the total dose of orlistat;

and the total concentration of acarbose and orlistat, respectively, in the composition is 100% w/w.

2. A modified-release composition according to claim 1, wherein

a) G1 is a DR_{DC}-$PR_{GASTRIC}$ part that is designed to release acarbose in a prolonged manner,

b) G2 is a DR_{EC}-$RR_{PROX\ SI}$ part that is designed to release acarbose and orlistat in the proximal small intestine, and

c) G3 is a DR_{DC}-$PR_{GASTRIC}$ and/or DR_{EC}-$PR_{INTESTINAL}$ part that is designed to release orlistat in the proximal part of the small intestine until the end of jejunum.

3. A modified-release composition according to claim 1 or 2, wherein part G1 of the composition is in the form of granules, pellets, minitablets etc. or part G1 is incorporated into a two-layer tablet, where part G1 is contained in one of the two layers.

4. A modified-release composition according to claim 3, wherein the layer containing part G1 is provided with a delayed release coating.

5. A modified-release composition according to any of the preceding claims, wherein part G2, of the composition is in the form of granules, pellets, minitablets etc. containing an enteric polymer and/or is provided with an enteric coating, or G2 is incorporated

into a two-layer tablet, where part G2 is contained in one of the two layers and the layer containing part G2 is provided with an enteric coating.

6. A modified-release composition according to any one of the preceding claims, wherein part G3 is in the form of granules, pellets, minitablets etc. or it is contained in a two layer tablet, wherein part G3 is contained in one of the two layers.

7. A modified-release composition according to any of the preceding claims, wherein G1 comprises acarbose and a hydrophobic polymer, and the hydrophobic polymer is selected from the group consisting of ethylcellulose, acrylates or acrylic acid derivatives, gelatin, coating agent selected from the group consisting of co-polymers based on polymethacrylic acid and methacrylates, ethyl acrylate and methyl acrylate, co-polymers of acrylic and methacrylic acid esters, hydroxypropyl methylcellulose phthlate, cellulose acetate phthalate, polyvinyl acetate pthtalate, and mixtures thereof.

8. A modified-release composition according to claim 7, wherein the hydrophobic polymer is ethylcellulose.

9. A modified-release composition according to any of the preceding claims, wherein G1 comprises acarbose and a lipid, fat, and the lipid is selected from fatty acids and/or esters, fatty alcohols, cetyl alcohol, stearyl alcohol, mineral oils, hydrogenated vegetable oils, vegetable oils, acetylated hydrogenated soybean oil glycerides, Castor oil, hydrogenated vegetable oils, or mixtures thereof.

10. A modified-release composition according to claims 7-9, wherein the hydrophobic polymer, lipid or wax is present in a concentration of from about 10% to about 50% w/w of the total weight of G1.

11. A modified-release composition according to any of the preceding claims, wherein G2 comprises an enteric polymer selected from the group consisting of acrylate, acrylic acid polymers, acrylic acid co-polymers, hydroxypropyl methylcellulose phthalate, cellulose acetate phthalate, polyvinyl acetate pthatalate, and mixtures thereof.

12. A modified-release composition according to claim 11, wherein the enteric polymer is selected from co-polymers based on polymethacrylic acid and methacrylates, ethyl

acrylate and methyl acrylate, co-polymers of acrylic and methacrylic acid esters, and mixtures thereof.

13. A modified-release composition according to claim 11 or 12, wherein the enteric polymer is present in a concentration of from about 15 to about 50% w/w based on the total weight of G2.

14. A modified-release composition according to any of the preceding claims, wherein G2 comprises a surfactant selected from the group consisting of anionic, cationic and non-ionic surfactants, and mixtures thereof.

15. A modified-release composition according to claim 14, wherein the non-ionic surfactant is selected from polysorbate 20, polysorbate 21, polysorbate 40, polysorbate 60, polysorbate 61, polysorbate 65, polysorbate 80, polysorbate 81, polysorbate 85, polysorbate 120, sorbitan monoisostearate, sorbitan monolaurate, sorbitan monopalmitate, sorbitan monostearate, sorbitan monooleate, sorbitan sesquioleate, sorbitan trioleate, glyceryl monooleate and polyvinylalcohol, and mixtures thereof; the anionic surfactant is selected from docusate sodium and sodium lauryl sulphate, and mixtures thereof; and the cationic surfactant is selected from benzalkonium chloride, benzethonium chloride and cetrimide, and mixtures thereof.

16. A modified-release composition according to claim 14 or 15, wherein the concentration of surfactants is from about 0.5% to about 30% w/w of the total weight of G2.

17. A modified-release composition according to any of the preceding claims, wherein G3 comprises a water-soluble polymer selected from hydroxypropylmethylcellulose, methylcellulose, carboxymethylcellulose and hydroxypropylcellulose, and mixtures thereof.

18. A modified-release composition according to claim 17, wherein the water-soluble polymer is present in a concentration of from about 70 to about 90% w/w based on the total weight of G3.

19. A modified-release composition according to any of the preceding claims in the form of a multiple-unit tablet, a bi-layer multiple-unit tablet, a coated tablet, a multiple-unit capsule or a multiple-unit oral powder.

20. A modified-release composition according to any of the preceding claims, wherein G1, G2, and G3 are in the form of pellets, granules, spheres or the like.

21. A modified-release composition according to any of the preceding claims in the form of a multiple-unit tablet, capsule, sachet or powder.

22. A modified-release composition as defined in any of the preceding claims for use in triggering the gastro-intestinal brake as defined in this application.

23. A method for the treatment or prevention of: overweight and obesity; type 2 diabetes; Elevated blood glucose level (such as impaired glucose tolerance), Polycystic ovarian syndrome; Disorders of lipoprotein metabolism and other lipidemias(such as hyperglyceridemia); Nonalcoholic fatty liver disease (NAFLD); Nonalcoholic steatohepatitis; or metabolic syndrome, the method comprising administering a modified-release composition as defined in any of claims 1-21.

24. A modified-release composition as defined in any of claims 1-21, wherein G3 is excluded, and orlistat is excluded from part G2.

25. A modified-release composition as defined in any of claims 1-21, wherein part G1 is excluded and acarbose is excluded from part G2.

26. A modified-release composition as defined in claim 24 or 25 for use in triggering the gastro-intestinal brake as defined in this application.

27. A cosmetic method for reducing body weight, the method comprising administering to a subject in need thereof a modified-release composition as defined in any of claims 1-21, 24-26.

28. A modified-release composition as defined in any of claims 1-21, 24-26 for use in the treatment of overweight and obesity; type 2 diabetes; Elevated blood glucose level (such as impaired glucose tolerance), Polycystic ovarian syndrome; Disorders of lipoprotein metabolism and other lipidemias(such as hyperglyceridemia); Nonalcoholic fatty liver disease (NAFLD); Nonalcoholic steatohepatitis; or metabolic syndrome.