CLAIMS

WHAT IS CLAIMED IS:

1. The use of metformin or salt thereof in the manufacture of a medicament for lowering plasma glucose levels in a subject in need thereof, wherein the medicament is adapted to release a therapeutically effective amount of the metformin to one or more regions of the intestine.

2. The use of metformin or a salt thereof in the manufacture of a medicament for treating disorders of glucose metabolism in a subject in need thereof, wherein the medicament is adapted to release a therapeutically effective amount of the metformin to one or more regions of the intestine.

3. The use according to claim 2, wherein said disorder is hyperglycemia.

4. The use of metformin or a salt thereof in the manufacture of a medicament for treating a condition associated with a chemosensory receptor in a subject in need thereof, wherein the medicament is adapted to release a therapeutically effective amount of the metformin to one or more regions of the intestine.

5. The use according to any one of claims 1 - 4, wherein said metformin salt is metformin hydrochloride.

6. The use according to any one of claims 1 - 4, wherein said one or more regions of the intestine are the duodenum, jejunum, ileum and/or lower intestine.

7. The use according to any one of claims 1 - 4, wherein said one or more regions of the intestine are the jejunum, ileum and/or lower intestine.

8. The use according to any one of claims 1 - 4, wherein said medicament releases the metformin at an onset of about pH 5.0, about pH 5.5, about pH 6.0, about pH 6.5, about pH 7.0, or combination thereof.

9. The use according to any one of claims 1 - 4, wherein the therapeutically effective amount of metformin is about 1 mg to about 2000 mg.

10. The use according to any one of claims 1 - 4, wherein the therapeutically effective amount of metformin is about 50 mg to about 1000 mg.

11. The use according to any one of claims 1 - 4, wherein the average bioavailability of the metformin is less than the average bioavailability of an immediate release metformin formulation having an equivalent amount of metformin.

12. The use according to any one of claims 1 - 4, wherein said medicament further comprises an antidiabetic or antiobesity agent.

13. The use according to claim 12, wherein said antidiabetic agent is selected from the group consisting of thiazolidinediones, sulfonyureas, meglitinides, alpha-glucosidase inhibitors, DPP-IV inhibitors, and incretin mimetics.

14. The use according to claim 12, wherein the antiobesity agent is selected from the group consisting of phentermine, fenfluramine, sibutramine, rimonabant, topiramate, zonisamide bupropion, naltrexone, lorcaserin, and orlistat.

15. The use according to any one of claims 1 - 4, the medicament further comprising a chemosensory receptor ligand selected from the group consisting of a sweet receptor ligand, a bitter receptor ligand, an umami receptor ligand, a fat receptor ligand, a sour receptor ligand and a bile acid receptor ligand.

16. The use according to claim 4 wherein the condition associated with a chemosensory receptor is selected from metabolic syndrome, diabetes type I, diabetes type II, obesity, binge eating, undesired food cravings, food addiction, a desire to reduce food intake or to lose weight or maintain weight loss, desire to maintain healthy weight, desire to maintain normal blood glucose metabolism, anorexia, pre-diabetes, glucose intolerance, gestational diabetes mellitus (GDM), impaired fasting glycemia (IFG), post-prandial hyperglycemia, accelerated gastric emptying, dumping syndrome, delayed gastric emptying, dyslipidemia, post-prandial dyslipidemia, hyperlipidemia, hypertriglyceridemia, post-prandial hypertriglyceridemia, insulin resistance, bone loss disorders, osteopenia, osteoporosis, muscle wasting disease, muscle degenerative disorders, polycystic ovary syndrome (PCOS), non-alcoholic fatty liver disease (NAFL), non-alcoholic steatohepatitis (NASH), immune disorders of the gut, celiac disease,

bowel irregularity, irritable bowel syndrome (IBS), inflammatory bowel disease (IBD), ulcerative colitis, Crohn's disease, short bowel syndrome, peripheral neuropathy and diabetic neuropathy.

17. The use according to claim 1, 12 or 13, wherein said condition is diabetes or pre-diabetes.

18. The use according to claim 1, 12 or 14, wherein said condition is obesity.

19. The use of metformin or a salt thereof in the manufacture of a medicament for treating a disease, disorder or defect in energy homeostasis in a subject, wherein the medicament is adapted to release a therapeutically effective amount of the metformin to one or more regions of the intestine.

20. A pharmaceutical composition comprising metformin or a salt thereof and another antidiabetic or antiobesity agent, wherein the average bioavailability of the metformin is less than the average bioavailability of an immediate release metformin formulation having an equivalent amount of metformin.

21. The pharmaceutical composition according to claim 20, wherein the metformin or salt thereof is enterically-coated.

22. The pharmaceutical composition according to claim 21, wherein the metformin or salt thereof is released from said pharmaceutical dosage form at an onset of about pH 5.0, about pH 5.5, about pH 6.0, about pH 6.5, about pH 7.0, or a combination thereof following administration to a subject.

23. The pharmaceutical composition according to claim 20, wherein said antidiabetic agent is selected from the group consisting of thiazolidinediones, sulfonyureas, meglitinides, alpha-glucosidase inhibitors, DPP-IV inhibitors, and incretin mimetics.

24. The pharmaceutical composition according to claim 20, wherein the antiobesity agent is selected from the group consisting of phentermine, fenfluramine, sibutramine, rimonabant, topiramate, zonisamide bupropion, naltrexone, lorcaserin, and orlistat.

25. The pharmaceutical composition according to claim 20, further comprising a chemosensory receptor ligand selected from the group consisting of a sweet receptor ligand, a bitter receptor ligand, an umami receptor ligand, a fat receptor ligand, a sour receptor ligand and a bile acid receptor ligand.

Claims

1. The use of metformin or a salt thereof in the manufacture of a medicament for lowering blood glucose levels in a subject in need thereof, wherein the medicament is adapted to release a therapeutically effective amount of metformin downstream of the stomach to one or more regions of the intestine.

2. The use of metformin or a salt thereof in the manufacture of a medicament for treating disorders of glucose metabolism in a subject in need thereof, wherein the medicament is adapted to release a therapeutically effective amount of metformin downstream of the stomach to one or more regions of the intestine.

3. The use according to claim 2, wherein said disorder is hyperglycemia.

4. The use of metformin or a salt thereof in the manufacture of a medicament for treating a condition associated with a chemosensory receptor in a subject in need thereof, wherein the medicament is adapted to release a therapeutically effective amount of metformin downstream of the stomach to one or more regions of the intestine.

5. The use according to any one of claims 1 - 4, wherein said metformin or a salt thereof is metformin hydrochloride.

6. The use according to any one of claims 1 - 4, wherein said one or more regions of the intestine are the duodenum, jejunum, ileum and/or lower intestine.

7. The use according to any one of claims 1 - 4, wherein said one or more regions of the intestine are the jejunum, ileum and/or lower intestine.

8. The use according to any one of claims 1 - 4, wherein said metformin or a salt thereof is enterically-coated.

9. The use according to any one of claims 1 - 4, wherein said medicament releases the metformin at an onset of about pH 5.0, about pH 5.5, about pH 6.0, about pH 6.5, about pH 7.0, or combination thereof.

10. The use according to any one of claims 1 - 4, wherein the amount of metformin or salt thereof used in the preparation of the medicament is about 1 mg to about 2000 mg.

11. The use according to any one of claims 1 - 4, wherein the amount of metformin or salt thereof used in the preparation of the medicament is about 50 mg to about 1000 mg.

12. The use according to any one of claims 1 - 4, wherein the amount of metformin or salt thereof used in the preparation of the medicament is about 500 mg.

13. The use according to any one of claims 1 - 4, wherein the amount of metformin or salt thereof used in the preparation of the medicament is about 600 mg.

14. The use according to any one of claims 1 - 4, wherein the amount of metformin or salt thereof used in the preparation of the medicament is about 800 mg.

15. The use according to any one of claims 1 - 4, wherein the amount of metformin or salt thereof used in the preparation of the medicament is about 1000 mg.

16. The use according to any one of claims 1 - 4, wherein said medicament further comprises an antidiabetic or antiobesity agent.

17. The use according to claim 16, wherein said antidiabetic agent is selected from the group consisting of thiazolidinediones, sulfonyureas, meglitinides, alpha-glucosidase inhibitors, DPP-IV inhibitors, incretin mimetics, and SGLT inhibitors.

18. The use according to claim 17 wherein said antidiabetic agent is a DPP-IV inhibitor.

19. The use according to claim 16, wherein the antiobesity agent is selected from the group consisting of phentermine, fenfluramine, sibutramine, rimonabant, topiramate, zonisamide bupropion, naltrexone, lorcaserin, and orlistat, and combinations thereof.

20. The use according to any one of claims 1 - 4, the medicament further comprising a chemosensory receptor ligand selected from the group consisting of a sweet receptor ligand, bitter receptor

ligand, an umami receptor ligand, a fat receptor ligand, a sour receptor ligand and a bile acid receptor ligand.

21. The use according to claim 4 wherein the condition associated with a chemosensory receptor is selected from metabolic syndrome, diabetes type I, diabetes type II, obesity, binge eating, undesired food cravings, food addiction, a desire to reduce food intake or to lose weight or maintain weight loss, desire to maintain healthy weight, desire to maintain normal blood glucose metabolism, anorexia, pre-diabetes, glucose intolerance, gestational diabetes mellitus(GDM), impaired fasting glycemia (IFG), post-prandial hyperglycemia, accelerated gastric emptying, dumping syndrome, delayed gastric emptying, dyslipidemia, post-prandial dyslipidemia, hyperlipidemia, hypertriglyceridemia, post-prandial hypertriglyceridemia, insulin resistance, bone loss disorders, osteopenia, osteoporosis, muscle wasting disease, muscle degenerative disorders, polycystic ovary syndrome (PCOS), non-alcoholic fatty liver disease(NAFL), non-alcoholic steatohepatitis (NASH), immune disorders of the gut, celiac disease, bowel irregularity, irritable bowel syndrome (IBS), inflammatory bowel disease (IBD), ulcerative colitis, Crohn's disease, short bowel syndrome, peripheral neuropathy and diabetic neuropathy.

22. The use according to claim 21, wherein said condition is diabetes.

23. The use according to claim 21, wherein said condition is pre-diabetes.

24. The use according to claim 21, wherein said condition is obesity.

25. The use of metformin or a salt thereof in the manufacture of a medicament for treating a disease, disorder or defect in energy homeostasis in a subject, wherein the medicament is adapted to release a therapeutically effective amount of metformin downstream of the stomach to one or more regions of the intestine.

26. The use according to any one of claims 1 to 25, wherein the medicament further releases about 10% of the metformin in the stomach.

27. A pharmaceutical composition comprising metformin or a salt thereof and another antidiabetic or antiobesity agent, wherein the pharmaceutical composition is adapted to release a therapeutically

effective amount of metformin downstream of the stomach to one or more regions of the intestine.

28. The pharmaceutical composition according to claim 27, wherein the metformin or salt thereof is enterically-coated.

29. The pharmaceutical composition according to claim 28, wherein the metformin is released from said pharmaceutical dosage form at an onset of about pH 5.0, about pH 5.5, about pH 6.0, about pH 6.5, about pH 7.0, or a combination thereof following administration to a subject.

30. The pharmaceutical composition according to claim 27, wherein said antidiabetic agent is selected from the group consisting of thiazolidinediones, sulfonyureas, meglitinides, alpha-glucosidase inhibitors, DPP-IV inhibitors, incretin mimetics, and SGLT inhibitors.

31. The pharmaceutical composition according to claim 30 wherein said antidiabetic agent is a DPP-IV inhibitor.

32. The pharmaceutical composition according to claim 27, wherein the antiobesity agent is selected from the group consisting of phentermine, fenfluramine, sibutramine, rimonabant, topiramate, zonisamide bupropion, naltrexone, lorcaserin, and orlistat, and combinations thereof.

33. The pharmaceutical composition according to claim 27, further comprising a chemosensory receptor ligand selected from the group consisting of a sweet receptor ligand, a bitter receptor ligand, an umami receptor ligand, a fat receptor ligand, a sour receptor ligand and a bile acid receptor ligand.

34. The pharmaceutical composition according to any one of claims 27 to 33, wherein the pharmaceutical composition further releases about 10% of the metformin in the stomach.