Claims

1. A pharmaceutical combination for use in the treatment of a diabetes type 2 patient, wherein the diabetes type 2 is insufficiently controlled by at least one oral antidiabetic drug, said combination comprising
   (a) desPro^{36}Exendin-4(1-39)-Lys$_6$-NH$_2$ or/and a pharmaceutically acceptable salt thereof,
   (b) insulin glargine or/and pharmaceutically acceptable salt thereof, and
   (c) metformin or/and a pharmaceutically acceptable salt thereof,
   wherein the treatment of the diabetes type 2 patient comprises the steps:
   (i) administration of compounds (b) and (c) for at least 4 weeks, and
   (ii) continuing treatment by administration of compounds (a), (b) and (c),
   wherein the amount of compound (b) to be administered in steps (i) or/and (ii) is adjusted so that a predetermined fasting plasma glucose level or/and a predetermined self monitored plasma glucose level is reached or at least approximated.

2. The pharmaceutical combination of claim 1, wherein step (i) comprises administration of compounds (b) and (c) for at least 4 weeks, at least 8 weeks, at least 12 weeks, or at least 16 weeks.

3. The pharmaceutical combination of claim 2, wherein step (i) comprises administration for at least about 12 weeks.

4. The pharmaceutical combination of claims 1 or 3, wherein step (i) is performed with the proviso that compound (a) is not administered.

5. The pharmaceutical combination of any one of the preceding claims, wherein steps (i) or/and (ii) further comprise the administration of a thiazolidinedione.

6. The pharmaceutical combination of any one of the preceding claims, wherein administration in steps (i) or/and (ii) is performed on a daily basis.

7. The pharmaceutical combination of any one of the preceding claims, wherein the amount of compound (b) to be administered in steps (i) or/and (ii) is adjusted on the basis of daily measurements of plasma glucose concentration.

8. The pharmaceutical combination of any one of the preceding claims, wherein the amount of compound (b) to be administered in steps (i) or/and (ii) is adjusted so that a fasting plasma glucose level of about 4.4 mmol/l to about 5.6 mmol/l or/and a self monitored plasma glucose level of about 8 mmol/l is reached or at least approximated.

9. The pharmaceutical combination of any one of the preceding claims, wherein the treatment of a diabetes type 2 patient improves glycemic control in a diabetes type 2 patient.

10. The pharmaceutical combination of claim 9, wherein glycemic control is postprandial glycemic control.

11. The pharmaceutical combination of claim 10, wherein postprandial glycemic control is control of postprandial plasma glucose or/and postprandial glucose excursion.

12. The pharmaceutical combination of any one of the preceding claims, wherein the treatment of a diabetes type 2 patient improves self-monitored plasma glucose.

13. The pharmaceutical combination of any one of the preceding claims, wherein the treatment of a diabetes type 2 patient induces weight loss or/and prevents weight gain.

14. The pharmaceutical combination of any one of the preceding claims, wherein the treatment of a diabetes type 2 patient prevents hypoglycemia.

15. The pharmaceutical combination according to any one of the preceding claims, wherein the patient to be treated is obese.

16. The pharmaceutical combination according to any one of the preceding claims, wherein the patient to be treated has a body mass index of at least 30 kg/m^2.

17. The pharmaceutical combination according to any one of the preceding claims, wherein the patient to be treated is an adult patient.

18. The pharmaceutical combination according to any one of the preceding claims, wherein the patient to be treated does not receive a treatment by an insulin or/and a pharmaceutically acceptable salt thereof at the onset of step (i).

19. The pharmaceutical combination of any one of the preceding claims, wherein in the patient to be treated, diabetes mellitus type 2 has been diagnosed at least 1 year or at least 2 years before onset of therapy.

20. The pharmaceutical combination of any one of the preceding claims, wherein the patient to be treated has a HbA_{1c} value of about 7 to about 10%.

21. The pharmaceutical combination of any one of the preceding claims, wherein at the onset of step (i), the patient has a fasting plasma glucose concentration of at least 8 mmol/L.

22. The pharmaceutical combination of any one of the preceding claims, wherein at the onset of step (i), the patient has a 2 hours postprandial plasma glucose concentration of at least 10 mmol/L, at least 12 mmol/L, or at least 14 mmol/L.

23. The pharmaceutical combination of any one of the preceding claims, wherein at the onset of step (i), the patient has a glucose excursion of at least 2 mmol/L, at least 3 mmol/L, at least 4 mmol/L or at least 5 mmol/L, wherein the glucose excursion is the difference of the 2 hours

postprandial plasma glucose concentration and plasma glucose concentration 30 minutes prior to a meal test.

24. The pharmaceutical combination of any one of the preceding claims, wherein the desPro^{36}Exendin-4(1-39)-Lys$_6$-NH$_2$ or/and the pharmaceutically acceptable salt thereof is prepared for parenteral administration.

25. The pharmaceutical combination according to any of the preceding claims, wherein the insulin glargine or/and the pharmaceutically acceptable salt thereof is prepared for parenteral administration.

26. The pharmaceutical combination according to any one of the preceding claims, wherein the desPro^{36}Exendin-4(1-39)-Lys$_6$-NH$_2$ or/and the pharmaceutically acceptable salt thereof is prepared for administration in a daily dose selected from the range of 10 µg to 20 µg.

27. The pharmaceutical combination of any one of the preceding claims, wherein the metformin or/and the pharmaceutically acceptable salt thereof is prepared for oral administration.

28. A method for treatment of a diabetes type 2 patient, wherein the diabetes type 2 is insufficiently controlled by at least one oral antidiabetic drug, wherein the method comprises the administration of a combination, said combination comprises

(a) desPro^{36}Exendin-4(1-39)-Lys$_6$-NH$_2$ or/and a pharmaceutically acceptable salt thereof,

(b) insulin glargine or/and pharmaceutically acceptable salt thereof, and

(c) metformin or/and a pharmaceutically acceptable salt thereof,

wherein the administration of the combination comprises the steps:

(i) administration of compounds (b) and (c) for at least 4 weeks, and

(ii) continuing treatment by administration of compounds (a), (b) and (c),

wherein the amount of compound (b) to be administered in steps (i) or/and (ii) is adjusted so that a predetermined fasting plasma glucose level or/and a predetermined self monitored plasma glucose level is reached or at least approximated.

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Claims

1. A pharmaceutical combination for use in the treatment of a diabetes type 2 patient, wherein the diabetes type 2 is insufficiently controlled by at least one oral antidiabetic drug, said combination comprising
   (a) desPro^{36}Exendin-4(1-39)-Lys$_6$-NH$_2$ or/and a pharmaceutically acceptable salt thereof,
   (b) insulin glargine or/and pharmaceutically acceptable salt thereof, and
   (c) metformin or/and a pharmaceutically acceptable salt thereof,
   wherein the treatment of the diabetes type 2 patient comprises the steps:
   (i) administration of compounds (b) and (c) for at least 4 weeks, and
   (ii) continuing treatment by administration of compounds (a), (b) and (c),
   wherein at the onset of step (i) the patient has a 2 hours postprandial plasma glucose concentration of at least 12 mmol/L, and
   wherein the amount of compound (b) to be administered in steps (i) or/and (ii) is adjusted so that a predetermined fasting plasma glucose level or/and a predetermined self monitored plasma glucose level is reached or at least approximated.

2. The pharmaceutical combination of claim 1, wherein step (i) comprises administration of compounds (b) and (c) for at least 4 weeks, at least 8 weeks, at least 12 weeks, or at least 16 weeks.

3. The pharmaceutical combination of claim 2, wherein step (i) comprises administration for at least about 12 weeks.

4. The pharmaceutical combination of claims 1 or 3, wherein step (i) is performed with the proviso that compound (a) is not administered.

5. The pharmaceutical combination of any one of the preceding claims, wherein steps (i) or/and (ii) further comprise the administration of a thiazolidinedione.

6. The pharmaceutical combination of any one of the preceding claims, wherein administration in steps (i) or/and (ii) is performed on a daily basis.

7. The pharmaceutical combination of any one of the preceding claims, wherein the amount of compound (b) to be administered in steps (i) or/and (ii) is adjusted on the basis of daily measurements of plasma glucose concentration.

8. The pharmaceutical combination of any one of the preceding claims, wherein the amount of compound (b) to be administered in steps (i) or/and (ii) is adjusted so that a fasting plasma glucose level of about 4.4 mmol/l to about 5.6 mmol/l or/and a self monitored plasma glucose level of about 8 mmol/l is reached or at least approximated.

9. The pharmaceutical combination of any one of the preceding claims, wherein the treatment of a diabetes type 2 patient improves glycemic control in a diabetes type 2 patient.

10. The pharmaceutical combination of claim 9, wherein glycemic control is postprandial glycemic control.

11. The pharmaceutical combination of claim 10, wherein postprandial glycemic control is control of postprandial plasma glucose or/and postprandial glucose excursion.

12. The pharmaceutical combination of any one of the preceding claims, wherein the treatment of a diabetes type 2 patient improves self-monitored plasma glucose.

13. The pharmaceutical combination of any one of the preceding claims, wherein the treatment of a diabetes type 2 patient induces weight loss or/and prevents weight gain.

14. The pharmaceutical combination of any one of the preceding claims, wherein the treatment of a diabetes type 2 patient prevents hypoglycemia.

15. The pharmaceutical combination according to any one of the preceding claims, wherein the patient to be treated is obese.

16. The pharmaceutical combination according to any one of the preceding claims, wherein the patient to be treated has a body mass index of at least 30 kg/m^2.

17. The pharmaceutical combination according to any one of the preceding claims, wherein the patient to be treated is an adult patient.

18. The pharmaceutical combination according to any one of the preceding claims, wherein the patient to be treated does not receive a treatment by an insulin or/and a pharmaceutically acceptable salt thereof at the onset of step (i).

19. The pharmaceutical combination of any one of the preceding claims, wherein in the patient to be treated, diabetes mellitus type 2 has been diagnosed at least 1 year or at least 2 years before onset of therapy.

20. The pharmaceutical combination of any one of the preceding claims, wherein the patient to be treated has a HbA_{1c} value of about 7 to about 10%.

21. The pharmaceutical combination of any one of the preceding claims, wherein at the onset of step (i), the patient has a fasting plasma glucose concentration of at least 8 mmol/L.

22. The pharmaceutical combination of any one of the preceding claims, wherein at the onset of step (i), the patient has a 2 hours postprandial plasma glucose concentration of at least 12 mmol/L, or at least 14 mmol/L.

23. The pharmaceutical combination of any one of the preceding claims, wherein at the onset of step (i), the patient has a glucose excursion of at least 2 mmol/L, at least 3 mmol/L, at least 4 mmol/L or at least 5 mmol/L, wherein the glucose excursion is the difference of the 2 hours postprandial plasma glucose concentration and plasma glucose concentration 30 minutes prior to a meal test.

24. The pharmaceutical combination of any one of the preceding claims, wherein the desPro^{36}Exendin-4(1-39)-Lys$_6$-NH$_2$ or/and the pharmaceutically acceptable salt thereof is prepared for parenteral administration.

25. The pharmaceutical combination according to any of the preceding claims, wherein the insulin glargine or/and the pharmaceutically acceptable salt thereof is prepared for parenteral administration.

26. The pharmaceutical combination according to any one of the preceding claims, wherein the desPro^{36}Exendin-4(1-39)-Lys$_6$-NH$_2$ or/and the pharmaceutically acceptable salt thereof is prepared for administration in a daily dose selected from the range of 10 µg to 20 µg.

27. The pharmaceutical combination of any one of the preceding claims, wherein the metformin or/and the pharmaceutically acceptable salt thereof is prepared for oral administration.