Claims

1. A pharmaceutical composition comprising
(a) lixisenatide or/and a pharmaceutically acceptable salt thereof, and
(b) insulin glargine or/and a pharmaceutically acceptable salt thereof,
wherein the compound (b) and compound (a) are present in a ratio of 2.6 to 3.4 U of compound (b) per µg of compound (a).

2. The composition of claim 1, wherein the concentration of compound (a) is in the range of 25 - 40 µg/ml, and wherein the concentration of compound (b) is in the range of 65 - 136 U/ml.

3. The composition of claim 1 or 2, with the proviso that the concentration of compound (a) is not a concentration selected from 39.22 µg/mL, 37.04 µg/mL and 35.09 µg/mL

4. The pharmaceutical composition of any one of the claims 1 to 3, wherein the compound (b) and compound (a) are present in a ratio of 3 U of compound (b) per µg of compound (a).

5. The pharmaceutical composition of any one of claims 1-4, comprising 100 U/mL of insulin glargine or/and a pharmaceutically acceptable salt thereof, and 33 µg/mL of lixisenatide or/and a pharmaceutically acceptable salt thereof.

6. The pharmaceutical composition of any one of the claims 1 to 5, with the proviso that the composition is not an on-site mixed composition.

7. The pharmaceutical composition of any one of the claims 1 to 6, which is provided within a container.

8. The pharmaceutical composition of any one of the claims 1 to 7, for use in the treatment of diabetes mellitus type 1 or/and 2.

9. The pharmaceutical composition for use of claim 8, by administration of a dose of 0.25 to 1.5 U/kg body weight insulin glargine.

10. The pharmaceutical composition for use of claim 8, by administration of a dose of 0.05 to 0.5 µg/kg body weight lixisenatide.

11. The pharmaceutical composition for use of any one of the claims 8 to 10, wherein the composition is administered parenterally.

12. The pharmaceutical composition for use of any one of the claims 8 to 11, wherein the patient to be treated is at least 50 years old.

13. The pharmaceutical composition for use of any one of the claims 8 to 12, wherein the patient to be treated is obese.

14. The pharmaceutical composition for use of claim 13, wherein the patient to be treated has a body mass index of at least 30 kg/m^2, at least 31 kg/m^2, at least 32 kg/m^2 or at least 33 kg/m^2.

15. The pharmaceutical composition for use of any one of the claims 8 to 14, wherein diabetes mellitus type 2 is not adequately controlled with metformin alone.

16. The pharmaceutical composition for use of claim 15, wherein a treatment with at least 1 .5 g/day of metformin does not adequately control the diabetes mellitus type 2.

17. The pharmaceutical composition for use of any one of the claims 8 to 16, wherein the patient to be treated has a HbA1c value in the range of at least 7 %, at least 8 % or at least 9% at the onset of treatment with the composition.

18. The pharmaceutical composition for use of any one of the claims 8 to 17, wherein the patient to be treated has a fasting plasma glucose concentration of at least 7 mmol/L, at least 8 mmol/L, at least 9 mmol/L, at least 10 mmol/L, or at least 11 mmol/L at the onset of treatment with the composition.

19. The pharmaceutical composition for use of any one of the claims 8 to 18, wherein the patient to be treated has a self-monitored plasma glucose concentration of at least 8 mmol/L, at least 9 mmol/L, at least 10 mmol/L, or at least 1 1 mmol/L at the onset of treatment with the composition.

20. The pharmaceutical composition for use of any one of the claims 8 to 19, wherein the patient to be treated has a 2-hour postprandial plasma glucose of at least 12 mmol/L, at least 13 mmol/L, at least 14 mmol/L, at least 15 mmol/L, at least 16 mmol/L, or at least 17 mmol/L at the onset of treatment with the composition.

21. The pharmaceutical composition for use of any one of the claims 8 to 20, wherein the patient to be treated has a 2-hour postprandial plasma glucose excursion of at least 5 mmol/L, at least 5.5 mmol/L, at least 6 mmol/L, at least 6.5 mmol/L, or at least 7 mmol/L at the onset of treatment with the composition.

22. The pharmaceutical composition for use of any one of the claims 8 to 21, wherein the patient to be treated does not receive a GLP-1 receptor agonist or/and an insulin.

23. Use of a composition of
(a) lixisenatide or/and a pharmaceutically acceptable salt thereof, and
(b) insulin glargine or/and a pharmaceutically acceptable salt thereof,
for the preparation of a composition for the treatment of diabetes mellitus type 1 or/and 2, wherein the compound (b) and compound (a) are present in the composition in a ratio of 2.6 to 3.4 U of compound (b) per µg of compound (a).

24. The use of claim 23, wherein the compound (b) and compound (a) are present in the composition in a ratio of 3 U of compound (b) per µg of compound (a).

25. The use of claim 23 or 24 wherein the composition comprises 100 U/mL of insulin glargine or/and a pharmaceutically acceptable salt thereof, and 33 µg/mL of lixisenatide or/and a pharmaceutically acceptable salt thereof.

26. The use of any one of the claims 23 to 24, wherein the patient to be treated is defined as in any one of the claims 12 to 22.

27. A pharmaceutical combination comprising
(I) a pharmaceutical composition comprising
(a) lixisenatide or/and a pharmaceutically acceptable salt thereof, and

(b) insulin glargine or/and a pharmaceutically acceptable salt thereof, wherein the compound (b) and compound (a) are present in a ratio of 1.6 to 2.4 U of compound (b) per µg of compound (a); and

(II) a pharmaceutical composition comprising

(a) lixisenatide or/and a pharmaceutically acceptable salt thereof, and

(b) insulin glargine or/and a pharmaceutically acceptable salt thereof, wherein the compound (b) and compound (a) are present in a ratio of 2.6 to 3.4 U of compound (b) per µg of compound (a).

28. The pharmaceutical combination of claim 27, for use in the treatment of diabetes mellitus type 1 or/and type 2.

29. Use of a pharmaceutical combination for the preparation of a medicament for the treatment of diabetes mellitus type 1 or/and 2, wherein the combination comprises

(I) a pharmaceutical composition comprising

(a) lixisenatide or/and a pharmaceutically acceptable salt thereof, and

(b) insulin glargine or/and a pharmaceutically acceptable salt thereof, wherein the compound (b) and compound (a) are present in a ratio of 1.6 to 2.4 U of compound (b) per µg of compound (a); or/and

(II) a pharmaceutical composition comprising

(a) lixisenatide or/and a pharmaceutically acceptable salt thereof, and

(b) insulin glargine or/and a pharmaceutically acceptable salt thereof, wherein the compound (b) and compound (a) are present in a ratio of 2.6 to 3.4 U of compound (b) per µg of compound (a).

30. The use of claim 29, wherein the pharmaceutical composition of (I) is to be administered if the diabetes mellitus type 1 or/and 2 patient requires a dose of insulin glargine of less than or equal to 40 U, and the pharmaceutical composition of (II) is administered if the diabetes mellitus type 1 or/and 2 patient requires a dose of insulin glargine of more than 40 U.

31. The use of claim 29 or 30, wherein the pharmaceutical composition of (I) is to be administered if the diabetes mellitus type 1 or/and 2 patient requires a dose of insulin glargine in the range of 10 to 40 U, and the pharmaceutical composition of (II) is administered if the diabetes mellitus type 1 or/and 2 patient requires a dose of insulin glargine in the range of more than 40 U up to 60 U.

32. The use of claim 33, wherein the pharmaceutical composition of (I) is to be administered if the diabetes mellitus type 1 or/and 2 patient requires a dose of insulin glargine of less than or equal to 30 U, and the pharmaceutical composition of (II) is administered if the diabetes mellitus type 1 or/and 2 patient requires a dose of insulin glargine of more than 30 U.

33. The use of claim 29 or 32, wherein the pharmaceutical composition of (I) is to be administered if the diabetes mellitus type 1 or/and 2 patient requires a dose of insulin glargine in the range of 10 to 30 U, and the pharmaceutical composition of (II) is administered if the diabetes mellitus type 1 or/and 2 patient requires a dose of insulin glargine in the range of more than 30 U up to 60 U.

34. The use of any one of the claims 30 to 33, wherein the insulin glargine dose is a daily dose of insulin glargine, or/and wherein the lixisenatide is a daily dose of lixisenatide.

35. The use of any one of the claims 29 to 34, wherein the patient to be treated is defined as in any one of the claims 12 to 22.