Claims

1. Use of a pharmaceutical composition comprising
(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 medicament for the treatment of diabetes mellitus type 2 patient,

wherein the compound (b) is present in a concentration of 100 U/ml, and compound (a) is present in a concentration of 33 µg/ml, and

wherein the pharmaceutical composition is to be administered in combination with metformin or/and a pharmaceutically acceptable salt thereof.

2. The use of claim 1, with the proviso that the composition is not an on-site mixed composition.

3. The use of claim 1, which is provided within a container.

4. The use of claim 1, wherein a dose of 0.25 to 1.5 U/kg body weight insulin glargine is to be administered to the patient.

5. The use of claim 1, wherein a dose of 0.05 to 0.5 µg/kg body weight lixisenatide is to be administered to the patient.

6. The use of any one of the claims 4 to 5, wherein the composition is to be administered parenterally.

7. The use of any one of the claims 4 to 6, wherein the patient to be treated is at least 50 years old.

8. The use of any one of the claims 4 to 7, wherein the patient to be treated is obese.

9. The use of claim 8, 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.

10. The use of any one of the claims 4 to 9, wherein diabetes mellitus type 2 is not adequately controlled with metformin alone.

11. The use of claim 10, wherein a treatment with at least 1.5 g/day of metformin does not adequately control the diabetes mellitus type 2.

12. The use of any one of the claims 4 to 11, 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.

13. The use of any one of the claims 4 to 12, 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.

14. The use of any one of the claims 4 to 13, 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.

15. The use of any one of the claims 4 to 14, 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.

16. The use of any one of the claims 4 to 15, 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.

17. The use of any one of the claims 4 to 16, wherein the patient to be treated does not receive a GLP-1 receptor agonist or/and an insulin.

18. Use of a pharmaceutical combination for the preparation of a medicament for the treatment of diabetes mellitus type 2 patient, 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) is present in a concentration of 100 U/ml, and compound (a) is present in a concentration of 50 µg/ml, 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) is present in a concentration of 100 U/ml, and compound (a) is present in a concentration of 33 µg/ml,

wherein the pharmaceutical composition (I) and (II) is to be administered in combination with metformin or/and a pharmaceutically acceptable salt thereof.

19. The use of claim 18, wherein the pharmaceutical composition of (I) is to be administered if the diabetes mellitus type 2 patient requires a dose of insulin glargine of less than or equal to 40 U, and the pharmaceutical composition of (II) is to be administered if the diabetes mellitus type 2 patient requires a dose of insulin glargine of more than 40 U.

20. The use of claim 18 or 19, wherein the pharmaceutical composition of (I) is to be administered if the diabetes mellitus type 2 patient requires a dose of insulin glargine in the range of 10 to 40 U, and the pharmaceutical composition of (II) is to be administered if the diabetes mellitus type 2 patient requires a dose of insulin glargine in the range of more than 40 U up to 60 U.

21. The use of claim 18, wherein the pharmaceutical composition of (I) is to be administered if the diabetes mellitus type 2 patient requires a dose of insulin glargine of less than or equal to 30 U, and the pharmaceutical composition of (II) is to be administered if the diabetes mellitus type 2 patient requires a dose of insulin glargine of more than 30 U.

22. The use of claim 18 or 21, wherein the pharmaceutical composition of (I) is to be administered if the diabetes mellitus type 2 patient requires a dose of insulin glargine in the range of 10 to 30 U, and the pharmaceutical composition of (II) is to be administered if the diabetes mellitus type 2 patient requires a dose of insulin glargine in the range of more than 30 U up to 60 U.

23. The use of any one of the claims 19 to 22, wherein the insulin glargine dose is a daily dose of insulin glargine, or/and wherein the lixisenatide is a daily dose of lixisenatide.

24. The use of any one of the claims 18 to 23, wherein the patient to be treated is defined as in any one of the claims 7 to 17.