Claims

1. Use of an aqueous pharmaceutical formulation comprising 200 - 1000 U/mL [equimolar to 200 - 1000 IU human insulin] of insulin glargine, with the proviso that the concentration of said formulation is not 684 U/mL of insulin glargine in the manufacture of a medicament for the treatment reducing the risk of nocturnal hypoglycemia in Type I or Type II Diabetes Mellitus, wherein the time interval from the previous administration is in the range of 24.5 hours to 28 hours or in the range of 20 hours to 23.5 hours on at least two days per week and wherein the average time interval from the previous administration is 24 hours.
2. The use of claim 1 comprising 200 U/ml to 650 U/mL of insulin glargine.
3. The use of claim 1 comprising 700 U/ml to 1000 U/mL of insulin glargine.
4. The use of claim 2 comprising 270 - 330 U/mL of insulin glargine [equimolar to 270 - 330 IU human insulin].
5. The use of claim 4 comprising 300 U/mL of insulin glargine [equimolar to 300 IU human insulin].
6. The use of any of the foregoing claims, wherein the nocturnal hypoglycemia is selected from symptomatic hypoglycemia, severe symptomatic hypoglycemia, documented symptomatic hypoglycemia, probable symptomatic hypoglycemia, relative symptomatic hypoglycemia, and asymptomatic hypoglycemia.
7. The use of any of the foregoing claims, wherein the use of the formulation of claim 1 in the manufacture of a medicament for the treatment reducing the risk of nocturnal hypoglycemia in the patient having a HbA1 c value of at least 8% at the onset of treatment.

8. The use of any of the foregoing claims, wherein the use of the formulation of claim 1 in the manufacture of a medicament for the treatment reducing the risk of nocturnal hypoglycemia in the patient having an age of at least 60 years at the onset of treatment.
9. The use of any of the foregoing claims, wherein the use of the formulation of claim 1 in the manufacture of a medicament for the treatment reducing the risk of nocturnal hypoglycemia in the patient having a BMI of at least 30 kg/m^2 at the onset of treatment.
10. The use of any of the foregoing claims, wherein the use of the formulation of claim 1 in the manufacture of a medicament for the treatment reducing the risk of nocturnal hypoglycemia in the patient receiving a basal insulin directly prior to the treatment.
11. The use of any of the foregoing claims, wherein the use of the formulation of claim 1 in the manufacture of a medicament for the treatment reducing the risk of nocturnal hypoglycemia in the patient receiving a mealtime short-acting insulin directly prior to the treatment.
12. The use of claim 10 or 11, wherein the use of the formulation of claim 1 in the manufacture of a medicament for the treatment reducing the risk of nocturnal hypoglycemia in the patient having SMPG of at least 9 mmol/L at the onset of treatment.
13. The use of claim 10 or 11, wherein the use of the formulation of claim 1 in the manufacture of a medicament for the treatment reducing the risk of nocturnal hypoglycemia in the patient having a fasting plasma glucose concentration of at least 8 mmol/L at the onset of treatment.
14. The use of any of the foregoing claims, wherein the patient additionally receives a mealtime short-acting insulin.
15. The use of any of the foregoing claims further comprising an analogue of exendin-4.
16. The use of claim 15, wherein the analogue of exendin-4 is selected from a group comprising lixisentatide, exenatide and liraglutide.
17. The use of claim 16 comprising 0.1 g to 10 g lixisenatide per U insulin glargine.

18. The use of claim 17 comprising 0.2 to 1 g lixisenatide per U insulin glargine.
19. The use of claim 18 comprising 0.25g to 0.7g lixisenatide per U insulin glargine.
20. The use of any of the foregoing claims comprising one or more excipients selected from a group comprising zinc, m-cresol, glycerol, polysorbate 20 and sodium.
21. The use of claim 20 comprising 90 µg/mL zinc, 2.7mg/mL m-cresol and 20 mg/ml glycerol 85%.
22. The use of claim 21 comprising 90 µg/mL zinc, 2.7mg/mL m-cresol, 20 µg/mL polysorbate 20 and 20 mg/mL glycerol 85%.
23. The use of any of the foregoing claims, wherein the pH is between 3.4 and 4.6.
24. The use of claim 23, wherein the pH is 4.
25. The use of claim 24, wherein the pH is 4.5.
26. The use of any one of the claims 1 to 25, wherein the Diabetes Mellitus is Type II Diabetes Mellitus.
27. The use of claim 26, wherein the Diabetes Mellitus Type II is not adequately controlled with at least one oral antihyperglycemic alone.
28. The use of claim 27, wherein the at least one oral antihyperglycemic is metformin.
29. The use of claim 28, wherein a treatment with at least 1.5 g/day of metformin does not adequately control the Diabetes Mellitus.
30. The use of any of the claims 26 to 29, wherein the medicament is to be administered in combination with at least one oral antihyperglycemic agent.
31. The use of claim 30, wherein the at least one antihyperglycemic agent is metformin.
32. The use of claim 1 wherein the time interval of claim 1 is at least three days per week.
33. The use of claim 32 wherein the time interval of claim 1 is at least four days per week.
34. The use of any one of the claims 32 to 33, wherein the time interval from the previous administration is in the range of 25 h to 28 h or in the range of 20 h to 23 h.

35. The use of any one of the claims 32 to 34, wherein the time interval from the previous administration is in the range of 25 h to 27 h or in the range of 21 h to 23 h.

36. The use of any one of the claims 32 to 35, wherein the time interval from the previous administration is in the range of 25 h to 26.5 h or in the range of 21 .5 h to 23 h.

37. The use of any one of the claims 32 to 36, comprising insulin glargine in an amount as defined in any one of the claims 2 to 5.

38. The use of any one of the claims 32 to 37, wherein the patient is defined as in any one of the claims 7 to 14.

39. The use of any one of the claims 32 to 38, further comprising an analogue of exendin-4, as defined in any one of the claims 15 to 19.

40. The use of any one of the claims 32 to 39, further comprising one or more excipients as defined in any one of the claims 20 to 22.

41. The use of any one of the claims 32 to 40, having a pH as defined in any one of the claims 23 to 25.

42. The use of claim 41, wherein the nocturnal hypoglycemia is selected from symptomatic hypoglycemia, severe symptomatic hypoglycemia, documented symptomatic hypoglycemia, probable symptomatic hypoglycemia, relative symptomatic hypoglycemia, and asymptomatic hypoglycemia.

43. The use of any one of the claims 32 to 42, wherein the Diabetes Mellitus is Type II Diabetes Mellitus.

44. The use of claim 43, wherein the Diabetes Mellitus type II is not adequately controlled with a least one oral antihyperglycemic agent alone, as defined in any one of the claims 28 to 32.