CLAIMS

1. An aqueous cagrilintide formulation comprising:
   (i) cagrilintide;
   (ii) a buffer which is: glutamic acid/glutamate, in a concentration of 2-10 mM; or lactic acid/lactate, in a concentration of 2-10 mM; or acetic acid/acetate, in a concentration of 2-10 mM; and
   (iii) 90-99% w/w water;
   having a pH of 3.5-4.5, such as about pH 4.0.

2. An aqueous cagrilintide formulation comprising:
   (i) cagrilintide in a concentration of 0.1-20 mg/ml; and
   (ii) a buffer which is: glutamic acid/glutamate, in a concentration of 2-10 mM; or lactic acid/lactate, in a concentration of 2-10 mM; or acetic acid/acetate, in a concentration of 2-10 mM;
   having a pH of 3.5-4.5, such as about pH 4.0.

3. The cagrilintide formulation according claim 1 or 2, wherein the concentration of cagrilintide in the cagrilintide formulation is about 1.0 mg/ml, such as 2.0 mg/ml, such as at least 2 mg/ml, such as about 4 mg/ml, such as about 4.8 mg/ml, such as about 9.6 mg/ml, or about 18 mg/ml.

4. The cagrilintide formulation according to any one of claims 1-3, wherein the buffer is glutamic acid/glutamate in a concentration of 2-10 mM, such as 2.5-10 mM, such as 2.5-5 mM, such as 5-10 mM, such as 2-9 mM, such as 2-8 mM, such as 2.5-7.5 mM, such as 2-7 mM, such as 2-6 mM, such as 4-6 mM, such as about 5 mM.

5. The cagrilintide formulation according to any one of claims 1-4, further comprising a tonicity agent, such as glycerol, mannitol, propylene glycol, sorbitol, sucrose or trehalose.

6. An aqueous cagrilintide formulation comprising:
   - cagrilintide in a concentration of 0.1-20 mg/ml, such as about 1.0 mg/ml, such as about 2.0 mg/ml, such as at least 2 mg/ml, such as about 4.0 mg/ml, such as about 4.8 mg/ml, such as about 6.8 mg/ml, such as about 9.6 mg/ml, such as about 18 mg/ml;

- glutamic acid/glutamate in a concentration of 2-10 mM, such as 2.5-10 mM, such as 2.5-5 mM, such as 5-10 mM, such as 2-9 mM, such as 2-8 mM, such as 2.5-7.5 mM, such as 2-7 mM, such as 2-6 mM, such as 4-6 mM, such as 2.5-5.0 mM, such as about 5 mM;
- glycerol in a concentration of 20-31 mg/ml, such as about 24 mg/ml;
- a pH of 3.5-4.5, such as pH 4.0.

7. The cagrilintide formulation according to any one of claims 1-6 for use in an injection device.

8. The cagrilintide formulation according to any one of claims 1-6 for use as a medicament.

9. The cagrilintide formulation according to any one of claims 1-6 for use in the treatment and/or prevention of obesity and/or diabetes.

10. The cagrilintide formulation according to any one of claims 1-6 for use in the treatment of subjects with an initial body mass index of 30 kg/m^2 or greater, or subjects with an initial body mass index of 27 kg/m^2 or greater and at least one weight-related comorbidity.

11. An aqueous semaglutide formulation comprising:
- semaglutide;
- phosphate, in a concentration of 20-45 mM, such as 20-40 mM, such as 25-45 mM, such as 25-40 mM, such as 20-35 mM, such as 20-30 mM, such as 25-35 mM, such as about 30 mM; and
- 90-99% w/w water;

having a pH of 7.0-8.0, such as about 7.4.

12. An aqueous semaglutide formulation comprising:
- semaglutide, in a concentration of 0.1-10 mg/ml; and
- phosphate, in a concentration of 20-45 mM, such as 20-40 mM, such as 25-45 mM, such as 25-40 mM, such as 20-35 mM, such as 20-30 mM, such as 25-35 mM, such as about 30 mM;

having a pH of 7-8, such as about 7.4.

13. The semaglutide formulation according to claim 11 or 12, wherein the concentration of semaglutide in the formulation is 0.5-10 mg/ml, such as 0.5-5.0 mg/ml, such as 0.5-4.8 mg/ml, such as about 0.5 mg/ml, such as about 1 mg/ml, such as about 2 mg/ml, such as about 3.4 mg/ml, such as about 4.8 mg/ml.

14. The semaglutide formulation according to any one of claims 11-13, further comprising histidine.

15. The semaglutide formulation according to claim 14, wherein the concentration of histidine is 1-20 mM.

16. The semaglutide formulation according to claim 15, wherein the concentration of histidine is 8-12 mM.

17. The semaglutide formulation according to any one of claims 11-16, further comprising a tonicity agent, such as propylene glycol, potassium chloride and/or sodium chloride.

18. An aqueous semaglutide formulation comprising:
    - semaglutide in a concentration of 0.1-10 mg/ml, such as 0.5-10 mg/ml, such as 0.5-5.0 mg/ml, such as 0.5-4.8 mg/ml, such as about 0.5 mg/ml, such as about 1 mg/ml, such as about 2 mg/ml, such as about 3.4 mg/ml, such as about 4.8 mg/ml;
    - a phosphate buffer, such as disodium hydrogen phosphate, dihydrate, in a concentration of 20-45 mM, such as 20-40 mM, such as 25-45 mM, such as 25-40 mM, such as 20-35 mM, such as 20-30 mM, such as 25-35 mM, such as about 30 mM;
    - sodium chloride in a concentration of 4.5-8.5 mg/ml, such as 5.0-8.5 mg/ml, such as 5.5-8.5 mg/ml, such as 6.0-8.5 mg/ml, such as 7.0-8.25 mg/ml, such as 4.5-7.0 mg/ml, such as 5.0-7.5 mg/ml, such as 5.0-7.0 mg/ml, such as 5.5-7 mg/ml, such as 6.4-7.9 mg/ml, such as 6.4-7.5 mg/ml, such as 6-7 mg/ml, such as above 6.4 mg/ml, such as about 5.4 mg/ml, such as about 6.4 mg/ml, such as about 6.7 mg/ml, and
    - histidine in a concentration of less than about 20 mM, such as 1-20 mM, such as 5-15 mM, such as 8-12 mM, such as about 10 mM,

    having a pH of 7.0-8.0, such as about 7.4.

19. The semaglutide formulation according to any one of claims 11-18 for use in an injection device.

20. The semaglutide formulation according to any one of claims 11-18, optionally in combination with the cagrilintide formulation according to any one of claims 1- 5, for use as a medicament.

21. The semaglutide formulation according to any one of claims 11-18 for use in the treatment and/or prevention of obesity and/or diabetes.

22. The semaglutide formulation according to any one of claims 11-18 for use in the treatment of subjects with an initial body mass index of 30 kg/m^2 or greater, or subjects with an initial body mass index of 27 kg/m^2 or greater and at least one weight-related comorbidity.

23. A medical device comprising semaglutide in a first chamber and cagrilintide in a second chamber.

24. A medical device comprising a first chamber and a second chamber, wherein the first chamber comprises the semaglutide formulation according to any one of claims 11-18 and the second chamber comprises the cagrilintide formulation according to any one of claims 1-6.

25. A medical device comprising a first chamber and a second chamber, wherein the first chamber comprises an aqueous semaglutide formulation comprising:
    - semaglutide in a concentration of 0.1-10 mg/ml, such as 0.5-10 mg/ml, such as 0.5-5.0 mg/ml, such as 0.5-4.8 mg/ml, such as about 0.5 mg/ml, such as about 1 mg/ml, such as about 2 mg/ml, such as about 3.4 mg/ml, such as about 4.8 mg/ml;
    - a phosphate buffer, such as disodium hydrogen phosphate, dihydrate, in a concentration of 20-45 mM, such as 20-40 mM, such as 25-45 mM, such as 25-40 mM, such as 20-35 mM, such as 20-30 mM, such as 25-35 mM, such as about 30 mM;
    - sodium chloride in a concentration of 4.5-8.5 mg/ml, such as 5.0-8.5 mg/ml, such as 5.5-8.5 mg/ml, such as 6.0-8.5 mg/ml, such as 7.0-8.25 mg/ml, such as 4.5-7.0 mg/ml, such as 5.0-7.5 mg/ml, such as 5.0-7.0 mg/ml, such as 5.5-7 mg/ml, such as

6.4-7.9 mg/ml, such as 6.4-7.5 mg/ml, such as 6-7 mg/ml, such as above 6.4 mg/ml, such as about 5.4 mg/ml, such as about 6.4 mg/ml, such as about 6.7 mg/ml;

- histidine in a concentration of less than about 20 mM, such as 1-20 mM, such as 5-15 mM, such as 8-12 mM, such as about 10 mM.
- a pH of 7.0-8.0, such as about 7.4; and wherein

the second chamber comprises an aqueous cagrilintide formulation comprising:

- cagrilintide in a concentration of 0.1-20 mg/ml, such as about 1.0 mg/ml, such as about 2.0 mg/ml, such as at least 2 mg/ml, such as about 4.0 mg/ml, such as about 4.8 mg/ml, such as about 6.8 mg/ml, such as about 9.6 mg/ml, such as about 18 mg/ml;
- glutamic acid/glutamate, in a concentration of 2-10 mM, such as 2.5-10 mM, such as 2.5-5 mM, such as 5-10 mM, such as 2-9 mM, such as 2-8 mM, such as 2.5-7.5 mM, such as 2-7 mM, such as 2-6 mM, such as 4-6 mM, such as 2.5-5.0 mM, such as about 5 mM;
- a tonicity agent which is glycerol, in a concentration of 20-31 mg/ml, such as about 24 mg/ml;
- a pH of 3.5-4.5, such as pH 4.0.

26. The medical device according to claim 23-25, wherein the medical device is an injection device having a drug outlet, wherein the first chamber is a distal chamber closest to the drug outlet, and the second chamber is a proximal chamber farthest from the drug outlet.

27. The medical device of claim 26, wherein the concentration of cagrilintide in the formulation in the proximal chamber is greater than the concentration of the semaglutide in the formulation in the distal chamber.

28. Use of a fixed-dose combination of 0.025-5.0 mg cagrilintide and 0.05-5.0 mg semaglutide in the manufacture of a medicament for the treatment and/or prevention of obesity and/or diabetes in subjects in need thereof, wherein the cagrilintide and semaglutide are to be administered parenterally, such as subcutaneously, in a single injection.

29. The use of claim 28, wherein the medicament is to be administered to subjects with an initial body mass index of 30 kg/m^2 or greater, or subjects with an initial body mass index of 27 kg/m^2 or greater and at least one weight-related comorbidity.

30. The use according to any one of claims 28-29, wherein the ratio (in mg) of cagrilintide to semaglutide to be administered is about 1:1.

31. The use according to any one of claims 28-30, wherein the dose of cagrilintide to be administered is 2.4 mg and the dose of semaglutide to be administered is 2.4 mg.

32. The use according to any one of claims 28-31, wherein the cagrilintide and semaglutide are to be administered, in a single injection, approximately once weekly, such as once every 5-9 days, such as once every 6-8 days, preferably, once every 7 days.

33. Use of an effective, fixed-dose combination of 0.08-5.0 mg cagrilintide and 0.125-5.0 mg semaglutide in the manufacture of a medicament for the treatment or prevention of overweight in subjects with an initial body mass index (BMI) of 30 kg/m^2 or greater (obesity), or subjects with an initial BMI of 27 kg/m^2 or greater (overweight) and at least one weight-related comorbidity, wherein the cagrilintide and the semaglutide are to be administered parenterally, such as subcutaneously, in a single injection.

34. The use according to claim 33, wherein the dose of cagrilintide to be administered in said single injection is from 0.16 mg to 4.5 mg per week, such as about 0.25 mg, 0.5 mg, 1.0 mg, 1.2 mg, 1.7 mg, 2.4 mg or 4.5 mg.

35. The use according to claim 33 or 34, wherein the dose of semaglutide to be administered in said single injection is about 0.25 mg, 0.5 mg, 1.0 mg, 1.7 mg or 2.4 mg.

36. The use according to any one of claims 33-35, wherein the ratio (in mg) of cagrilintide to semaglutide to be administered is about 1:1.

37. The use according to any one of claims 33-36, wherein:
    (i) the dose of cagrilintide to be administered is 0.25 mg and the dose of semaglutide administered is 0.25 mg;
    (ii) the dose of cagrilintide to be administered is 0.5 mg and the dose of semaglutide administered is 0.5 mg;
    (iii) the dose of cagrilintide to be administered is 1.0 mg and the dose of semaglutide administered is 1.0 mg;

(iv) the dose of cagrilintide to be administered is 1.7 mg and the dose of semaglutide administered is 1.7 mg; or

(v) the dose of cagrilintide to be administered is 2.4 mg and the dose of semaglutide administered is 2.4 mg.

38. The effective, fixed dose combination for use according to any one of claims 33-36, wherein:

– 0.25 mg cagrilintide and 0.25 mg semaglutide are to be administered once a week for four weeks (weeks 0-3);
– 0.5 mg cagrilintide and 0.5 semaglutide are to be administered once a week for four weeks (weeks 4-7);
– 1.0 mg cagrilintide and 1.0 semaglutide are to be administered once a week for the four weeks (weeks 8-11);
– 1.7 mg cagrilintide and 1.7 mg semaglutide are to be administered once a week for the four weeks (weeks 12-15); or
– 2.4 mg cagrilintide and 2.4 mg semaglutide mg are to be administered once a week thereafter.