SEMAGLUTIDE IN MEDICAL THERAPY

The present invention relates to semaglutide for use in medical therapy in the form of weight management including treatment of obesity.

BACKGROUND

Weight management, including treatment of obesity, remains a challenge for many. Recently approved medical therapies exist, including Saxenda® which is the GLP-1 receptor agonist (GLP-1 RA) liraglutide authorised for chronic weight management in persons who are suffering from obesity or overweight with at least one weight-related comorbid condition. The most frequent adverse events for GLP-1 RAs are gastrointestinal disorders, and in particular nausea. Improved medical therapies for weight management are still desired.

SUMMARY

In an aspect, there is provided a use of semaglutide in the manufacture of a medicament for weight management of a subject in need thereof, wherein said medicament is to be administered subcutaneously to said subject

a. in an amount of 2.0-10.0 mg of semaglutide once weekly, or

b. in an amount of 2.2-2.7 mg of semaglutide per week.

In some examples, the present disclosure relates to a method for weight management of a subject in need thereof, wherein said subject is administered semaglutide in an amount of 2.0-4.0 mg once weekly. In some examples, the present disclosure relates to a method for weight management of a subject in need thereof, wherein said subject is administered semaglutide in an amount of 2.2-2.7 mg per week.

DESCRIPTION

The present inventors surprisingly found that it is possible to administer semaglutide at high dosages, for example 2.0-4.0 mg once weekly, while achieving improved weight loss due to an unexpected beneficial ratio between the effect of semaglutide on body weight reduction and the safety profile observed for semaglutide at these high dosages. The present inventors also surprisingly found that the effect of semaglutide on body weight reduction continued to improve also through the high dosages of 0.3 and even 0.4 mg once daily. The present inventors also surprisingly found that the increase in safety profile, including gastrointestinal adverse events, at these high dosages surprisingly was lower than the improvement in body weight reduction. This is shown in the experimental section, where

the change in the number of reported gastrointestinal adverse events was lower than change in body weight reduction for the high dosages of 0.3 and 0.4 mg once daily. To our knowledge no publications exists which describe the relationship between body weight reduction and safety profile of a GLP-1 receptor agonist in a population of obese human subjects which do not suffer from type 2 diabetes other than that for liraglutide, also discussed herein.

CLAIMS

1. Use of semaglutide in the manufacture of a medicament for weight management of a subject in need thereof, wherein said medicament is to be administered subcutaneously to said subject
    a. in an amount of 2.0-10.0 mg of semaglutide once weekly, or
    b. in an amount of 2.2-2.7 mg of semaglutide per week.

2. The use according to claim 1, wherein said weight management is chronic weight management.

3. The use according to any one of the preceding claims, wherein said weight management is selected from the group consisting of: reducing body weight, treating and/or preventing obesity, treating and/or preventing overweight, and preventing weight gain.

4. The use according to any one of the preceding claims, wherein said amount of semaglutide to be administered per week is selected from the group consisting of 2.2-2.7 mg, 2.2-2.6 mg, and 2.3-2.5 mg.

5. The use according to any one of the preceding claims, wherein said semaglutide is to be administered once daily or once weekly.

6. The use according to any one of claims 1-3, wherein semaglutide is to be administered to said subject in an amount of 2.0-10.0 mg once weekly.

7. The use according to any one of claims 1-3, wherein said amount of semaglutide to be administered is in an amount of 2.0-4.0 mg once weekly.

8. The use according to any one of the preceding claims, wherein said semaglutide is to be administered via subcutaneous injection.

9. The use according to any one of the preceding claims, wherein semaglutide is to be administered in the form of a composition further comprising one or more pharmaceutically acceptable excipients.

10. The use according to any one of the preceding claims, wherein said composition is in the form of a solution or a suspension, such as an aqueous solution.

11. The use according to any one of the preceding claims, wherein the pH of said composition is in the range of 6.0-10.0, such as 6.5-9.0 or 7.0-8.0.

12. The use according to any one of the preceding claims, wherein the pH of said composition is about 7.4.

13. The use according to any one of the preceding claims, wherein the concentration of semaglutide in said composition is 0.01-50 mg/ml, such as 0.05-20 mg/ml or 0.1-10 mg/ml.

14. The use according to any one of the preceding claims, wherein the concentration of semaglutide in said composition is 0.01-5 mg/ml, such as 0.05-2 mg/ml.

15. The use according to any one of the preceding claims, wherein said subject has at least one weight-related comorbid condition selected from the group consisting of hypertension, type 2 diabetes mellitus, dyslipidemia, sleep apnoea, and urine incontinence.

16. The use according to any one of the preceding claims, wherein said subject has type 2 diabetes.