Description

Pharmaceutical composition comprising a GLP-1 agonist, an insulin and methionine

SUMMARY

In a first aspect, there is provided a liquid composition comprising a GLP-1 agonist or/and a pharmacologically tolerable salt thereof, insulin or/and a pharmacologically tolerable salt thereof and optionally at least one pharmaceutically acceptable excipient, characterized in that it contains L-methionine and has a pH between 3.5 and 4.5, wherein the GLP-1 agonist is desPro^{36}exendin-4(1-39)-Lys$_6$-NH$_2$ and the insulin is Gly(A21)-Arg(B31)-Arg(B32)-human insulin.

In a second aspect, there is provided a combination comprising a first pharmaceutical composition as defined herein and a second pharmaceutical composition as defined herein and optionally at least one further pharmaceutical composition as defined herein, each comprising at least one insulin and at least one GLP-1 agonist and containing the at least one insulin or/and the at least one GLP-1 agonist in different fractions, relative to the total weight of the composition.

In a third aspect, there is provided the use of a composition as defined herein or the combination as defined herein in the manufacture of a medicament for treating diabetes mellitus.

DETAILED DESCRIPTION

The present application relates to a liquid composition comprising a GLP-1 agonist or/and a pharmacologically tolerable salt thereof, an insulin or/and a pharmacologically tolerable salt thereof, and, optionally, at least one pharmaceutically acceptable excipient, wherein the composition comprises methionine.

The present application further relates to the composition according to the present invention for treating diabetes mellitus. The present application further relates to the use of a composition according to the present invention in the manufacture of a pharmaceutical for treating diabetes mellitus. The present application further relates to a method for manufacturing a composition according to the present invention, comprising formulating a GLP-1 agonist or/and a pharmacologically tolerable salt thereof with an insulin or/and a pharmaceutically acceptable salt thereof, methionine, and, optionally, at least one pharmaceutically acceptable excipient. The present application further relates to a method for treating a patient with a composition according to the present invention, comprising administering the composition to the patient.

Customary compositions of insulin and GLP-1 compounds comprise an isotonicity agent, a buffer for adjusting the pH, and a preservative. A further frequently used constituent of insulin compositions is zinc, which forms a complex with insulin. This results in a delayed action of insulin being achieved.