Introducing Xultophy®

(insulin degludec/liraglutide)

Please read this brochure to understand how to:

- administer Xultophy®
- select the recommended starting dose
- perform dose adjustments

novo nordisk®

What is Xultophy® and what is it used for?

This brochure provides important information regarding product administration of Xultophy® (insulin degludec/liraglutide).

Xultophy® contains a combination of two glucose-lowering injectable agents in one pre-filled pen:[1]
- a long-acting basal insulin analogue (insulin degludec)
- a Glucagon-Like Peptide-1 (GLP-1) analogue (liraglutide)

Xultophy® is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus to improve glycaemic control as an adjunct to diet and exercise in addition to other oral medicinal products for the treatment of diabetes.[1] For study results with respect to combinations, effects on glycaemic control, and the populations studied, see sections 4.4, 4.5 and 5.1 in the Israeli physician leaflet.[1]

How is Xultophy® administered?

Xultophy® is administered and adjusted as 'dose steps'. This specific dosing terminology has been defined to allow units of insulin degludec and mg of liraglutide to be combined in a single term to describe the dosing of Xultophy®.

One dose step contains 1 unit of insulin degludec and 0.036 mg of liraglutide. The pre-filled pen can provide from 1 up to 50 dose steps in one injection in increments of one dose step.[1] The dose counter on the pen shows the number of dose steps. In the example below the pen is set to 16 dose steps.

For an overview of the dose of each component for every dose step, please refer to the dose step wheel in the pocket on the back of this brochure.

Xultophy® is given once daily by subcutaneous administration, and the maximum daily dose of Xultophy® is 50 dose steps. Xultophy® can be administered at any time of day – preferably at the same time each day.[1]

Xultophy® is for subcutaneous use only. Xultophy® must not be administered intravenously or intramuscularly.[1]

How to select the recommended Xultophy® starting dose?

The recommended starting dose:

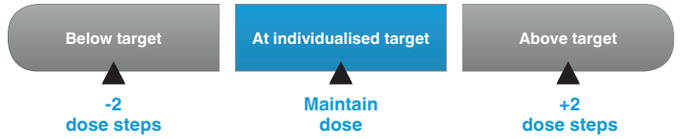
- **When adding Xultophy® on to oral antidiabetic drugs (OADs):** 10 dose steps (10 units of insulin degludec + 0.36 mg of liraglutide). For patients on sulphonylurea, the rate of hypoglycaemia may be lowered by reducing the dose of sulphonylurea[1]
- **When transferring from a GLP-1 receptor agonist:** 16 dose steps (16 units of insulin degludec + 0.6 mg of liraglutide). The starting dose of 16 dose steps should not be exceeded. Therapy with a GLP-1 receptor agonist should be discontinued prior to initiation of Xultophy®.[1] Close glucose monitoring is recommended during the transfer and in the following weeks[1]
- **When transferring from basal insulin therapy:** 16 dose steps (16 units of insulin degludec + 0.6 mg of liraglutide). The starting dose of 16 dose steps should not be exceeded. Therapy with basal insulin should be discontinued prior to initiation of Xultophy®. [1] Close glucose monitoring is recommended during the transfer and in the following weeks[1]

How to perform dose adjustments of Xultophy®?

Dose adjustment after initiation of Xultophy® treatment is important and should be done in accordance with the individual patient's needs. Optimise glycaemic control by adjusting the dose of Xultophy® twice weekly, based on fasting (pre-breakfast) plasma glucose (FPG).[1]

In the clinical trial program the number of dose steps of Xultophy® was adjusted twice weekly by patients according to a predefined algorithm (see below), based on self-measured FPG (mean of 3 consecutive days), striving for a mean FPG concentration of 4.0–5.0 mmol/L [72-90 mg/dL]. In the clinical trial investigating Xultophy® as add-on to sulphonylurea the target was 4.0–6.0 mmol/L [72-108 mg/dL].[1]

Adjust dose according to FPG target



How to report adverse events and medication errors?

Adverse events in connection with the use of Xultophy® should be reported to the Ministry of Health according to the National Regulation by using an online form https://sideeffects.health.gov.il
Or via the following Email address:
NNISRAEL_INFO@novonordisk.com
All medication errors, irrespective of any relation to adverse events, should also be reported.

Further information

For full details please see the enclosed Israeli physician leaflet

1.Xultophy® approved Israeli physician leaflet as published in the Israeli Ministry Of Health website.

This guide, format and content have been approved by the Ministry of Health on 05 March 2024

IL24XUM00006

Xultophy® dose step wheel