

Introducing Xultophy®

(insulin degludec/liraglutide)

- a new treatment for type 2 diabetes in one pen¹

Please read this brochure to understand how to:

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



This educational material is approved by SFDA (Saudi Food and Drug Authority)
Version 1.0 , XX-Jul-2020

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:

- 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. For study results with respect to combinations, effects on glycaemic control, and the populations studied, see Summary of Product Characteristics.

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 pen can provide from 1 up to 50 dose steps in one injection in increments of one dose step. 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 click the wheel at the end 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.

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

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
- **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
- **When transferring from basal insulin therapy:** 16 dose steps (16 units of insulin degludec + 0.58 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®. Close glucose monitoring is recommended during the transfer and in the following weeks.

How to perform dose adjustments of Xultophy®?

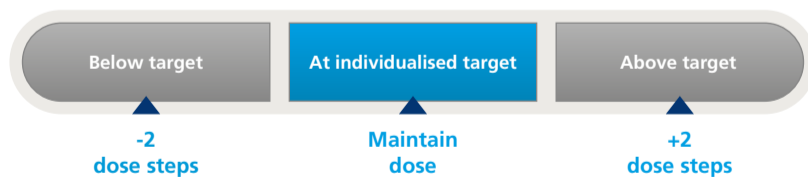
Dose adjustment after initiation of Xultophy® treatment is important and should be done in accordance with the individual patient's needs. Optimise glycaemic control by adjusting the dose of Xultophy® twice weekly, based on fasting (pre-breakfast) plasma glucose (FPG).

In the clinical trial programme the number of dose steps of Xultophy® was adjusted twice weekly by patients according to a pre-defined 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).

Further information

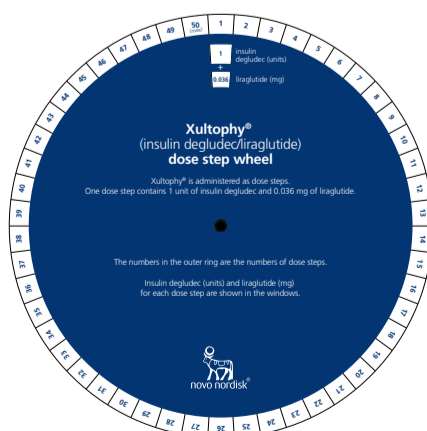
For full details please see the Summary of Product Characteristics and package leaflet.

Adjust dose according to FPG target



Please click on the dosing wheel

Password: Xultophy



For side effects reporting please contact us on:

SFDA National Pharmacovigilance and Drug Safety Center (NPC):

- Toll-free Number: 8002490000
- Call Center: 19999
- Email : NPC.Drug@sfda.gov.sa
- online: <http://ade.sfda.gov.sa>

Novo Nordisk Saudi Arabia:

- Tel: +966112728888 ext.: 345/245
- Email: nngulfsafety@novonordisk.com
- Online: <http://www.novonordisk.com.sa>

