Xultophy® (insulin degludec/liraglutide)
Dose Step Table

Xultophy® is administered as dose steps. One dose step contains 1 unit of insulin degludec and 0.036 mg of liraglutide

Table below shows units of insulin and mg of liraglutide for each dose step

Dose step	Insulin degludec (units)	Liraglutide (mg)
1	1	0.036
2	2	0.072
3	3	0.108
4	4	0.144
5	5	0.18
6	6	0.216
7	7	0.252
8	8	0.288
9	9	0.324
10	10	0.36
11	11	0.396
12	12	0.432
13	13	0.468
14	14	0.504
15	15	0.54
16	16	0.576
17	17	0.612
18	18	0.648
19	19	0.684
20	20	0.72
21	21	0.756
22	22	0.792
23	23	0.828
24	24	0.864
25	25	0.90

Dose step	Insulin degludec (units)	Liraglutide (mg)
26	26	0.936
27	27	0.972
28	28	1.008
29	29	1.044
30	30	1.08
31	31	1.116
32	32	1.152
33	33	1.188
34	34	1.224
35	35	1.26
36	36	1.296
37	37	1.332
38	38	1.368
39	39	1.404
40	40	1.44
41	41	1.476
42	42	1.512
43	43	1.548
44	44	1.584
45	45	1.62
46	46	1.656
47	47	1.692
48	48	1.728
49	49	1.764
50 (max.)	50	1.80

Novo Nordisk Limited, First Floor, Block A, The Crescent Building, Northwood Business Park, Santry, Dublin 9, D09 X8W3, Ireland. Tel: 01 8629 700, Fax: 01 8629 725
infoireland@novonordisk.com, www.novonordisk.ie

IE23XUM00001; Date of preparation: January 2023

novo nordisk®

Xultophy®

(insulin degludec/liraglutide)

Important information for healthcare professionals on safety and risk minimisation

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:

- 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.

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 refer to the dose step table 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.

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

All patients who have been prescribed Xultophy® should be trained on the correct use of the Xultophy® prefilled pen.

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 risk 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). Treatment with Xultophy® should be initiated at the moment the next dose of a long-acting GLP-1 receptor agonist would have been taken. 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®.
- **When transferring from any insulin regimen that includes a basal insulin component:** 16 dose steps (16 units of insulin degludec + 0.6 mg of liraglutide). The recommended starting dose should not be exceeded but may be reduced to avoid hypoglycaemia in selected cases. Therapy with other insulin regimens should be discontinued prior to initiation of Xultophy®.

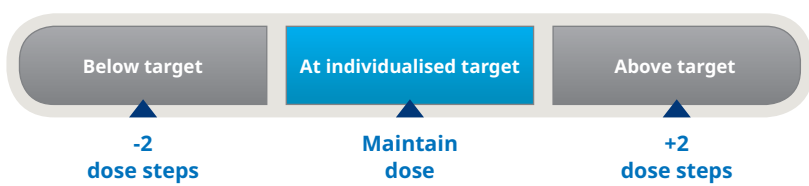
Close glucose monitoring is recommended during transfer from a GLP-1 receptor agonist or from basal insulin therapy, and in the following weeks.

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 need. 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. In the clinical trial investigating Xultophy® as add-on to sulphonylurea the target was 4.0-6.0 mmol/L.

Adjust dose according to FPG target



How to report adverse events and medication errors?

Adverse reactions to Xultophy®, including medication errors irrespective of whether or not they resulted in an adverse event, should be reported to Novo Nordisk on 01 862 9700. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance. Website: www.hpra.ie

Further information

For full details please see the Summary of Product Characteristics and package leaflet available on www.medicines.ie or www.hpra.ie.