

Victoza® factsheet

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Victoza® (liraglutide):

- Is a once-daily human GLP-1 (Glucagon-Like Peptide-1) analogue approved for the treatment of type 2 diabetes in adults.¹
- Has 97% similar to the body's own hormone (GLP-1). GLP-1 is a natural hormone in the body that plays a critical role in maintaining a healthy level of sugar in the blood. In type 2 diabetes, GLP-1 production and function is often impaired.²
- Lowers blood sugar levels by stimulating the release of insulin from beta cells and reducing the release of glucagon from alpha cells when blood sugar levels are high and by slowing gastric emptying.¹
 - Insulin lowers blood sugar by increasing sugar uptake primarily in muscles, liver and fat.
 - Glucagon increases blood sugar primarily by releasing sugar stores in the liver.
- Also, reduces body weight and body fat mass in people with type 2 diabetes through mechanisms involving reduced hunger and lowered energy intake.¹
- Is a once-daily injection given any time of day independent of meals.¹
- Was extensively tested in a clinical trial programme including more than 6,500 people.

- Has been directly compared, in terms of safety and efficacy, against commonly-used diabetes treatments like glimepiride, rosiglitazone, glargine, exenatide and sitagliptin in phase 3a and b clinical trials.³⁻⁹
- Has been documented in clinical trials to:
 - Reduce blood sugar levels
 - Reduce weight
 - Reduce blood pressure
 - Improve the function of insulin-producing beta cells³⁻⁹

Note: Victoza® has been approved by different regulatory agencies as a once-daily injection for the treatment of adults with type 2 diabetes mellitus to achieve glycaemic control. Victoza® has received:

Approval by EMA (Europe) in combination with:

- Metformin or a sulphonylurea in patients with insufficient glycaemic control despite maximal tolerated dose of monotherapy with metformin or sulphonylurea.
- Metformin and a sulphonylurea or metformin and a thiazolidinedione in patients with insufficient glycaemic control despite dual therapy.

Approval in Japan:

- as monotherapy or as an add-on to sulphonylurea (SU) in people with type 2 diabetes.

Approval by US Food and Drug Administration:

- As an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes. This provides for Victoza® to be used in monotherapy, as second-line treatment and in combination with commonly prescribed oral medications for diabetes.

References

1. Victoza® Summary of Product Characteristics (SPC) is available at novonordisk.com. Victoza has market authorisation in EU.
2. Højberg PV et al. Four weeks of near-normalisation of blood glucose improves the insulin response to glucagon-like peptide-1 and glucose-dependent insulinotropic polypeptide in patients with type 2 diabetes. *Diabetologia* 2009;52:199–207.
3. Marre M et al. Liraglutide, a once-daily human GLP-1 analogue, added to a sulphonylurea over 26 weeks produces greater improvements in glycaemic and weight control compared with adding rosiglitazone or placebo in subjects with type 2 diabetes (LEAD-1 SU). *Diabetic Medicine* 2009;268-278.
4. Nauck M et al. Efficacy and safety comparison of liraglutide, glimepiride, and placebo, all in combination with metformin in type 2 diabetes mellitus (LEAD-2 Met). *Diabetes Care* 2009; 32:84-90.
5. Garber A et al. Liraglutide versus glimepiride monotherapy for type 2 diabetes (LEAD-3 Mono): a randomised, 52-week, phase III, double-blind, parallel-treatment trial. *Lancet* 2009; 373 (9662): 473-481.
6. Zinman B et al. Efficacy and safety of the human GLP-1 analog liraglutide in combination with metformin and TZD in patients with type 2 diabetes mellitus (LEAD-4 Met+TZD). *Diabetes Care* 2009; 32: 1224-1230.
7. Russell-Jones D et al. Liraglutide vs insulin glargine and placebo in combination with metformin and sulphonylurea therapy in type 2 diabetes mellitus: a randomised controlled trial (LEAD-5 met+SU). *Diabetologia* 2009; 52(10):2046-2055.
8. Buse J et al. Liraglutide once a day versus exenatide twice a day for type 2 diabetes: a 26-week randomised, parallel-group, multinational, open-label trial (LEAD-6). *Lancet* 2009; 374 (9683): 39-47.
9. Novo Nordisk Interim financial report for the period 1 January 2009 to 30 June 2009 (6 August 2009)