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# Liraglutide STADA (*liraglutide*)

A plain-language overview of Liraglutide STADA and why it is authorised in the EU

## What is Liraglutide STADA and what is it used for?

Liraglutide STADA is a medicine used in addition to diet and exercise, in adults and children from 10 years of age who have type 2 diabetes. Liraglutide STADA is used:

- on its own when use of metformin (another medicine for type 2 diabetes) is not recommended;
- as an 'add-on' to other diabetes medicines.

Liraglutide STADA contains the active substance liraglutide and is a hybrid medicine. This means that it is similar to a reference medicine that contains the same active substance. The reference medicine for Liraglutide STADA is Victoza.

Liraglutide STADA differs from Victoza in the way the active substance is made. In Victoza, the active substance is made using living cells, whereas in Liraglutide STADA it is made using chemical processes.

## How is Liraglutide STADA used?

Liraglutide STADA can only be obtained with a prescription. The medicine is a solution for injection available in pre-filled pens. It is given once a day as an injection under the skin in the abdomen (belly), thigh or upper arm.

Liraglutide STADA can be given with or without food preferably at the same time each day. Treatment usually begins with a low dose. After at least one week, the doctor will increase the dose to help improve blood sugar control. In some cases, the dose may be increased further at weekly intervals, depending on how well the treatment is working.

When Liraglutide STADA is added to existing treatment containing metformin, thiazolidinedione or a sodium-glucose cotransporter 2 inhibitor (SGLT2i), the doses of these medicines do not have to be changed. When Liraglutide STADA is added to treatment with a sulphonylurea or insulin, the doctor should consider lowering the dose of the other medicine to reduce the risk of having hypoglycaemia (low blood glucose).

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For more information about using Liraglutide STADA, see the package leaflet or contact your doctor or pharmacist.

## How does Liraglutide STADA work?

Type 2 diabetes is a disease in which the pancreas does not make enough insulin to control the level of glucose (sugar) in the blood or when the body is unable to use insulin effectively. The active substance in Liraglutide STADA, liraglutide, is an 'incretin mimetic'. This means that it acts in the same way as incretins (hormones produced in the gut), among other effects, by increasing the amount of insulin released by the pancreas in response to food. This helps with the control of blood glucose levels.

## What benefits of Liraglutide STADA have been shown in studies?

Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, Victoza, and do not need to be repeated for Liraglutide STADA.

As for every medicine, the company provided studies on the quality of Liraglutide STADA. The company also carried out a study that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

Studies carried out with Liraglutide STADA are described in more detail in the medicine's assessment report.

## What are the side effects and restrictions with Liraglutide STADA?

For the full list of side effects and restrictions with Liraglutide STADA, see the package leaflet.

The most common side effects with Liraglutide STADA (which may affect more than 1 in 10 people) include nausea and diarrhoea. These side effects usually pass after a few days or weeks of starting treatment.

## Why is Liraglutide STADA authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Liraglutide STADA has been shown to have comparable quality and to be bioequivalent to Victoza. Therefore, the Agency's view was that, as for Victoza, the benefits of Liraglutide STADA outweigh the identified risks and it can be authorised for use in the EU.

## What measures are being taken to ensure the safe and effective use of Liraglutide STADA?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Liraglutide STADA have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Liraglutide STADA are continuously monitored. Suspected side effects reported with Liraglutide STADA are carefully evaluated and any necessary action is taken to protect patients.

## Other information about Liraglutide STADA

Liraglutide STADA received a marketing authorisation valid throughout the EU on 15 July 2026.

Further information on Liraglutide STADA, including the package leaflet and assessment report, can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/liraglutide-STADA.

For information about the availability of this medicine in your country, contact your national competent authority.

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