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Mounjaro (tirzepatide)

An overview of Mounjaro and why it is authorised in the EU

What is Mounjaro and what is it used for?

Mounjaro is a diabetes medicine used with diet and exercise to treat adults whose type 2 diabetes is not satisfactorily controlled.

Mounjaro can be used on its own in patients who cannot take metformin (another diabetes medicine). It can also be used as an 'add-on' to other diabetes medicines.

Mounjaro contains the active substance tirzepatide.

How is Mounjaro used?

Mounjaro is available as a solution for injection in prefilled pens and can only be obtained with a prescription. It is injected under the skin of the abdomen (belly), upper arm or thigh.

The starting dose of Mounjaro is 2.5 mg once a week. After four weeks, this dose should be increased to 5 mg. If needed, the dose can be further increased by 2.5 mg increments every four weeks, up to a maximum of 15 mg once a week. Mounjaro should be administered on the same day each week.

When Mounjaro is added to existing treatment for type 2 diabetes containing metformin or a sodium-glucose cotransporter 2 inhibitor (SGLT2i), the doses of these medicines do not have to be changed. When Mounjaro 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 hypoglycaemia (low blood glucose levels).

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

How does Mounjaro work?

Type 2 diabetes is a disease in which the body does not make enough insulin to control the level of glucose in the blood or when the body cannot use insulin effectively. The result is a high level of glucose in the blood.

The active substance in Mounjaro, tirzepatide, attaches to a receptor (target) of two hormones called glucose-dependent insulinotropic polypeptide (GIP) and glucagon-like peptide-1 (GLP-1) that are

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produced in the gut. It acts in the same way as GIP and GLP-1 by increasing the amount of insulin that the pancreas releases in response to food. This helps with the control of blood glucose levels.

What benefits of Mounjaro have been shown in studies?

Mounjaro was effective at controlling blood glucose in five main studies involving more than 6,000 adults with type 2 diabetes. In these studies, the main measure of effectiveness was the reduction in the proportion of haemoglobin in the blood that has glucose attached (HbA1c). This indicates how well blood glucose is controlled.

In two studies, Mounjaro lowered HbA1c by up to 2.1 and 2.6 percentage points after 40 weeks when added to existing treatment consisting of lifestyle changes only or insulin glargine with or without metformin, respectively. These results compared with no decrease or a decrease of 0.9 percentage points, respectively, in patients who received placebo (dummy treatment).

In a third study, Mounjaro lowered HbA1c by up to 2.5 percentage points after 40 weeks when added to metformin treatment, compared with a decrease of 1.9 percentage points in patients who received semaglutide.

In a fourth study, Mounjaro lowered HbA1c by up to 2.4 percentage points after 52 weeks, when added to treatment with metformin with or without an SGLT2i, compared with a decrease of 1.3 percentage points in patients who received insulin degludec.

Finally, in a fifth study, Mounjaro lowered HbA1c by up to 2.6 percentage points after 52 weeks, when added to treatment with up to 3 oral medicines (metformin, SGLT2is and sulphonylureas), compared with a decrease of 1.4 percentage points in patients who received insulin glargine.

What are the risks associated with Mounjaro?

The most common side effects with Mounjaro (which may affect more than 1 in 10 people) include problems with the digestive system, such as nausea (feeling sick), diarrhoea and vomiting. These were generally mild or moderate in severity and occurred more often when the dose of Mounjaro was changed.

For the full list of side effects and restrictions of Mounjaro, see the package leaflet.

Why is Mounjaro authorised in the EU?

Studies show that Mounjaro is effective in lowering blood glucose levels in patients with type-2 diabetes, when given alone or in combination with other diabetes medicines, without significantly increasing the patient's risk of having low glucose levels. Treatment with Mounjaro also resulted in weight loss and improvements in other measures such as blood pressure levels and the amount of fat in the blood and around the organs.

The side effects of Mounjaro are manageable and its safety will continue to be monitored. The European Medicines Agency therefore decided that Mounjaro's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Mounjaro?

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

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

Other information about Mounjaro

Mounjaro received a marketing authorisation valid throughout the EU on 15 September 2022.

Further information on Mounjaro can be found on the Agency's website: ema.europa.eu/en/medicines/human/EPAR/mounjaro

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