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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 medicine used together with diet and physical activity to treat adults who have type 2 diabetes which is not satisfactorily controlled. It can be used on its own in patients who cannot take metformin (another diabetes medicine) or as an 'add-on' to other diabetes medicines.

Mounjaro is also used together with diet and physical activity to help people to lose weight and keep their weight under control. It is used in people who have obesity (BMI of 30 kg/m^2 or more) or who are overweight (BMI between 27 and 30 kg/m^2) and have weight-related health problems such as diabetes, abnormally high levels of fat in the blood, high blood pressure or obstructive sleep apnoea (frequent interruption of breathing during sleep). BMI (body mass index) is a measure of your weight in relation to your height.

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 once a week, under the skin of the abdomen (belly), upper arm or thigh. Mounjaro should be injected on the same day each week.

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

How does Mounjaro work?

The active substance in Mounjaro, tirzepatide, acts in the same way as glucagon–like peptide–1 (GLP-1) and glucose–dependent insulinotropic polypeptide (GIP). These hormones are produced in the gut and bind to specific receptors (targets) in the body, such as, among others, the pancreas and brain. This increases the amount of insulin that the pancreas releases in response to food and helps lower blood glucose levels in people with type 2 diabetes. Targeting these receptors also reduces appetite and helps people manage their weight.

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What benefits of Mounjaro have been shown in studies?

Type 2 diabetes

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 (a 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 (another medicine for type 2 diabetes).

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 SGLT2 inhibitor (a group of medicines used to control blood glucose levels), 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, SGLT2 inhibitors and sulphonylureas (another group of medicines used to control blood glucose levels)), compared with a decrease of 1.4 percentage points in patients who received insulin glargine.

Weight management

Mounjaro was effective at helping people lose weight in a study involving more than 2,500 adults who had obesity (BMI over 30kg/m^2) or who were overweight (BMI between 27 and 30 kg/m^2) and had at least one weight-related health problem. In this study, people who used Mounjaro in combination with diet and physical activity for 72 weeks reduced their weight by at least 15% on average, depending on the dose they were given. This compares with 3% in people who were given a placebo. Over 85% of people taking Mounjaro were able to reduce their weight by at least 5%, compared with 35% of people given placebo.

What are the risks associated with Mounjaro?

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

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) and diarrhoea. Constipation and vomiting were seen in up to 1 in 10 people. Side effects linked to the digestive system were generally mild or moderate in severity and occurred more often when the dose of Mounjaro was changed.

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. In patients who have obesity or are overweight with weight-related complications, treatment with Mounjaro resulted in weight loss which

was mainly due to loss of fat mass. Further, Mounjaro improved other measures such as blood pressure levels and the amount of fat in the blood.

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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