



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 June 2026
EMA/140483/2026
EMA/VR/0000310637

Outcome of assessment on use of Mounjaro to reduce the risk of serious events affecting the heart and blood circulation

The European Medicines Agency (EMA) has finalised its assessment of an application to extend the use of Mounjaro (tirzepatide) to reduce the risk of serious cardiovascular events (problems affecting the heart and blood circulation) in adults with type 2 diabetes who already have cardiovascular disease. These events include heart attack, stroke or death due to cardiovascular disease.

Although EMA did not recommend that a separate indication should be granted, it agreed to include relevant data submitted with the application in the medicine's product information. This ensures healthcare professionals have access to up-to-date data on the effects of Mounjaro in patients with type 2 diabetes who have cardiovascular disease.

What is Mounjaro and what is it used for?

Mounjaro is a medicine used together with diet and physical activity to treat adults, adolescents and children aged 10 years and above 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 lose weight and keep their weight under control. It is used in people with obesity (BMI of 30 kg/m² or more) or overweight (BMI between 27 and 30 kg/m²) and who 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 a person's weight in relation to their height.

Mounjaro has been authorised in the EU since September 2022. It contains the active substance tirzepatide and is available as a solution for injection in prefilled pens. Mounjaro is injected once a week, under the skin of the abdomen (belly), upper arm or thigh.

Further information on Mounjaro's current uses can be found on the Agency's website:

www.ema.europa.eu/en/medicines/human/EPAR/mounjaro

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

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What change had the company applied for?

The company applied to extend the use of Mounjaro to lower the risk of serious cardiovascular events in adults with type 2 diabetes who already have cardiovascular disease.

Type 2 diabetes has been established as a common risk factor for serious cardiovascular events. Improving the control of blood sugar levels can lower the risk of serious cardiovascular events in adults with type 2 diabetes who already have cardiovascular disease.

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). The GLP-1 and GIP hormones are produced in the gut and bind to specific receptors (targets) in different parts of the body, such as 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.

What did the company present to support its application?

The company presented data from a main study involving 13,299 adults with type 2 diabetes that was not satisfactorily controlled and who also had cardiovascular disease and a BMI of 25 kg/m² or greater. The study looked at how long it took for either a heart attack, stroke or death due to cardiovascular causes to occur. In the study, Mounjaro was compared with dulaglutide (another diabetes medicine called a GLP-1 receptor agonist). Both medicines were given with standard of care (treatment that medical experts consider most appropriate) for type 2 diabetes.

What were EMA's conclusions?

Based on the results of the main studies, EMA's human medicines committee (CHMP) acknowledged that Mounjaro reduces the risk of serious cardiovascular events in adults with type 2 diabetes who already have cardiovascular disease. However, the CHMP considered that the use of Mounjaro in this group of people is already covered by its approved indication for the treatment of type 2 diabetes which is not satisfactorily controlled. Therefore, a separate indication is not needed.