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Outcome of assessment on use of Mounjaro in treatment of obstructive sleep apnoea

The European Medicines Agency (EMA) has finalised its assessment of an application to extend the indication of Mounjaro (tirzepatide) to include the treatment of obstructive sleep apnoea in adults with obesity.

Obstructive sleep apnoea is a condition where breathing is interrupted repeatedly during sleep due to the airways becoming blocked. Although EMA did not recommend that a separate indication should be granted for the treatment of obstructive sleep apnoea, 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 obstructive sleep apnoea and obesity.

What is Mounjaro and what is it used for?

Mounjaro is a medicine used together with diet and physical activity to treat adults with 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 who are 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

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What change had the company applied for?

The company applied to extend the use of Mounjaro, together with diet and physical activity, to treat moderate-to-severe obstructive sleep apnoea in adults with obesity.

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 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.

Obesity has been established as a common risk factor for obstructive sleep apnoea. Losing excess body weight can improve sleep-disordered breathing and reduce the severity of obstructive sleep apnoea.

What did the company present to support its application?

The company presented data from two main studies involving 469 adults with moderate-to-severe obstructive sleep apnoea and obesity. The first study involved patients who were unable or unwilling to use positive airway pressure (PAP) therapy (treatment designed to stop the narrowing of the airways during sleep). The second study involved patients who had been using PAP therapy for at least three consecutive months before their first study visit and planned to continue using it during the study. In both studies, Mounjaro was compared with placebo (a dummy treatment). Both studies looked at the change in the apnoea-hypopnea index (AHI) following one year of treatment. The AHI index measures the number of times per hour that breathing stops or becomes very shallow during sleep to determine the severity of sleep apnoea.

What were EMA's conclusions?

Based on the results of the main studies, EMA's human medicines committee (CHMP) acknowledged that Mounjaro improves obstructive sleep apnoea in adults with obesity. However, the CHMP considered that the use of Mounjaro in this group of people is already covered by the approved indication for weight management. Therefore, a separate indication for the treatment of moderate-to-severe obstructive sleep apnoea in adults with obesity is not needed.