EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 July 2022
EMA/CHMP/648485/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Mounjaro

tirzepatide

On 21 July 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Mounjaro, intended for the treatment of type 2 diabetes mellitus.

The applicant for this medicinal product is Eli Lilly Nederland B.V.

Mounjaro will be available as a solution for injection in a pre-filled pen. The active substance of Mounjaro is tirzepatide, a dual glucose-dependent insulinotropic polypeptide (GIP) and glucagon-like peptide 1 (GLP-1) receptor agonist (ATC code: A10B). By means of its action on these receptors, tirzepatide improves glycaemic control through several different mechanisms.

The benefit of Mounjaro is its ability to improve glycaemic control in patients with type 2 diabetes. The most common side effects are hypoglycaemia when used in combination with sulphonylurea or insulin, and gastrointestinal side effects such as nausea and diarrhoea.

The full indication is:

> Mounjaro is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise
>
> - as monotherapy when metformin is considered inappropriate due to intolerance or contraindications
> - in addition to other medicinal products for the treatment of diabetes.
>
> For study results with respect to combinations, effects on glycaemic control and the populations studied, see sections 4.4, 4.5 and 5.1.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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 An agency of the European Union

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