



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 October 2026
EMA/CHMP/229918/2026
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Foundayo orforglipron

On 15 October 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Foundayo, intended for the treatment of type 2 diabetes mellitus and for weight management.

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

Foundayo will be available as 0.8 mg, 2.5 mg, 5.5 mg, 9 mg, 14.5 mg and 17.2 mg film-coated tablets. The active substance of Foundayo is orforglipron, a glucagon-like peptide 1 (GLP-1) receptor agonist (ATC code: not yet assigned). By means of its action on these receptors, orforglipron improves glycaemic control and aids weight management through several different mechanisms.

The benefits of Foundayo are its clinically relevant effect on glycaemic control in patients with type 2 diabetes. Foundayo has also a beneficial effect on body weight when used in combination with a healthy diet and physical activity. The most common side effects are gastrointestinal side effects such as nausea, vomiting and diarrhoea.

The full indication is:

Weight management

Foundayo is indicated as an adjunct to healthy diet and physical activity for weight management, including weight loss and weight maintenance, in adults with an initial Body Mass Index (BMI) of

- $\geq 30 \text{ kg/m}^2$ (obesity), or
- $\geq 27 \text{ kg/m}^2$ to $< 30 \text{ kg/m}^2$ (overweight) in the presence of at least one weight-related comorbidity e.g. prediabetes or type 2 diabetes mellitus, hypertension, dyslipidaemia, obstructive sleep apnoea, or cardiovascular disease.

Type 2 diabetes mellitus

Foundayo is indicated for the treatment of adults with insufficiently controlled type 2 diabetes

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



mellitus as an adjunct to healthy diet and physical activity

- as monotherapy when metformin is considered inappropriate
- in combination with other medicinal products for the treatment of diabetes.

For trial results with respect to combinations, cardiovascular effects, 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 on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.