



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 July 2025
EMA/CHMP/237364/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Invokana canagliflozin

On 24 July 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending a change to the terms of the marketing authorisation for the medicinal product Invokana. The marketing authorisation holder for this medicinal product is Janssen-Cilag International NV.

The CHMP adopted an extension to an existing indication to include treatment of children from 10 years of age. The full indication for Invokana will therefore be as follows:²

Invokana is indicated for the treatment of adults **and children aged 10 years and older** 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 combination of therapies, effects on glycaemic control, cardiovascular and renal events, 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 updated summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

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

² New text in bold

