



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 May 2020
EMA/CHMP/229700/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Invokana canagliflozin

On 28 May 2020, 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 a change to an existing indication as follows:²

Invokana 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 combination of therapies, effects on glycaemic control, ~~and~~ 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 in the revised European public assessment report (EPAR), and will be available 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, removed text as strikethrough

