



20 May 2021  
EMA/CHMP/275069/2021  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (post authorisation)

---

# Jardiance

## empagliflozin

On 20 May 2021, 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 Jardiance. The marketing authorisation holder for this medicinal product is Boehringer Ingelheim International GmbH.

The CHMP adopted a new indication as follows:<sup>2</sup>

### Type 2 diabetes mellitus

Jardiance 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

in addition to other medicinal products for the treatment of diabetes

For study results with respect to combinations, effects on glycaemic control and cardiovascular events, and the populations studied, see sections 4.4, 4.5 and 5.1.

### **Heart failure**

**Jardiance is indicated in adults for the treatment of symptomatic chronic heart failure with reduced ejection fraction.**

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.

---

<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

<sup>2</sup> New text as bold

