



15 December 2016
EMA/398392/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Jardiance empagliflozin

On 15 December 2016 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 change to the existing indication as follows:²

"Jardiance is indicated ~~for~~ **in** the treatment of **adults with insufficiently controlled** type 2 diabetes mellitus **as** ~~to improve glycaemic control in adults as:~~

Monotherapy

~~When~~ **an adjunct to** diet and exercise

- ~~• as monotherapy when alone do not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to intolerance~~

Add-on combination therapy

- ~~In combination with~~ **in addition to** other glucose-lowering medicinal products **for the treatment of diabetes** including insulin, ~~when these, together with diet and exercise, do not provide adequate glycaemic control~~

~~(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 for available data on different combinations).~~"

For information, the full indication for Jardiance will therefore read as follows:

"Jardiance is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise

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 shown in bold; removed text as strikethrough



- 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.”

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.