27 June 2019
EMA/CHMP/354873/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Xigduo

dapagliflozin / metformin

On 27 June 2019, 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 Xigduo. The marketing authorisation holder for this medicinal product is AstraZeneca AB.

The CHMP adopted a change to the existing indication in type 2 diabetes as follows:[2]

"Xigduo is indicated in adults ~~aged 18 years and older with~~ **for the treatment of** type 2 diabetes mellitus as an adjunct to diet and exercise ~~to improve glycaemic control~~:

- in patients ~~inadequately~~ **insufficiently** controlled on their maximally tolerated dose of metformin alone
- in combination with other ~~glucose lowering~~ medicinal products~~, including insulin,~~ **for the treatment of diabetes** in patients ~~inadequately~~ **insufficiently** controlled with metformin and these medicinal products ~~(see sections 4.4, 4.5 and 5.1 for available data on different combinations)~~
- in patients already being treated with the combination of dapagliflozin and metformin as separate tablets.

For study results with respect to combination of therapies, 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.

[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

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