



18 May 2017
EMA/CHMP/301707/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Komboglyze

saxagliptin / metformin hydrochloride

On 18 May 2017, 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 Komboglyze. The marketing authorisation holder for this medicinal product is AstraZeneca AB.

The CHMP adopted a change to the existing indication to extend the use of Komboglyze in combination with other diabetes medicines. The indication will read as follows:

“Komboglyze is indicated in adults with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control:

- in patients inadequately controlled on their maximally tolerated dose of metformin alone
- in combination with other medicinal products for the treatment of diabetes, including insulin, in patients inadequately 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 saxagliptin and metformin as separate tablets.”

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

