



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Komboglyze

saxagliptin / metformin

On 22 September 2011, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Komboglyze, 2.5 mg/850mg and 2.5mg/1000 mg film-coated tablet intended for treatment of type 2 diabetes mellitus. The applicant for this medicinal product is Bristol-Myers Squibb / AstraZeneca EEIG. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Komboglyze is saxagliptin / metformin hydrochloride (A10BD10), a combination of oral blood glucose lowering products. Saxagliptin is a dipeptidyl peptidase-4 (DPP-4) inhibitor. DPP-4 inhibition reduces the cleavage and inactivation of the active (intact) form of the incretin hormone glucagon-like peptide 1 (GLP-1) and glucose dependent insulinotropic polypeptide (GIP), producing an elevation of incretin concentrations that leads to enhancement of glucose-dependent insulin secretion and a reduction in glucagon release. This way saxagliptin improves glycaemic control by reducing fasting and postprandial glucose concentrations in patients with type 2 diabetes. Metformin is a biguanide and has an antihyperglycaemic effect, lowering both basal and postprandial plasma glucose concentrations. It is thought to act via various mechanisms, including decreasing hepatic glucose production, decreasing intestinal absorption of glucose, and improving insulin sensitivity by increasing peripheral glucose uptake and utilisation. Komboglyze combines these two glucose-lowering agents with complementary mechanisms of action.

The benefits with Komboglyze are its reduction of blood glucose levels in patients inadequately controlled by metformin alone; and as being equivalent in its glucose-lowering effect compared to the combined use of saxagliptin 5mg once daily and metformin twice daily as an alternative option for patients being treated with these 2 medicines as separate tablets already. The most common side effects are upper respiratory infection, urinary tract infection, gastroenteritis, sinusitis, nasopharyngitis, headache, vomiting, nausea and rash. A common side effect of metformin use is metallic taste.

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.



A pharmacovigilance plan for Komboglyze will be implemented as part of the marketing authorisation.

The approved indication is: Komboglyze is indicated as an adjunct to diet and exercise to improve glycaemic control in adult patients aged 18 years and older with type 2 diabetes mellitus inadequately controlled on their maximally tolerated dose of metformin alone or those 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 summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Komboglyze and therefore recommends the granting of the marketing authorisation.