



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 October 2015
EMA/CHMP/605508/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Volibris ambrisentan

On 22 October 2015 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 Volibris. The marketing authorisation holder for this medicinal product is Glaxo Group Ltd.

The CHMP adopted an extension to the existing indication as follows²:

‘Volibris is indicated for the treatment of pulmonary arterial hypertension (PAH) in adult patients of WHO Functional Class (FC) II to III, **including use in combination treatment** ~~to improve exercise capacity~~ (see section 5.1). Efficacy has been shown in idiopathic PAH (IPAH) and in PAH associated with connective tissue disease.’

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 in bold, removed text as strikethrough**

