## Grŵp Strategaeth Meddyginiaethau Cymru Gyfan All Wales Medicines Strategy Group



## **Final Appraisal Recommendation**

Advice number: 2022 - October 2022

Ambrisentan (Volibris®) 2.5 mg, 5 mg, 10 mg film-coated tablets

Submission by GlaxoSmithKline UK Ltd

## Recommendation of the All Wales Medicines Strategy Group

Ambrisentan (Volibris®) is recommended as an option for use within NHS Wales for treatment of pulmonary arterial hypertension (PAH) in adult patients of WHO Functional Class (FC) II to III, including use in combination treatment. Efficacy has been shown in idiopathic PAH (IPAH) and in PAH associated with connective tissue.

Ambrisentan (Volibris®) is recommended as an option for use within NHS Wales, for the treatment of PAH in adolescents and children (aged 8 to less than 18 years) of WHO FC II to III including use in combination treatment. Efficacy has been shown in IPAH, familial, corrected congenital and in PAH associated with connective tissue disease.

## Additional note(s):

 This advice incorporates and replaces the AWMSG recommendation for ambrisentan (Volibris®) for treatment of pulmonary arterial hypertension (PAH) in adult patients of WHO Functional Class (FC) II to III, including use in combination treatment. (advice number 2508, originally published 2009).

The additional sentence 'Efficacy has been shown in idiopathic PAH (IPAH) and in PAH associated with connective tissue disease' is added to reflect the change in the wording of the licensed indication.

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 4819, which includes the All Wales Therapeutics and Toxicology Centre (AWTTC) assessment, clinical expert opinion (where available), the views of patients/patient carers (where available) and the lay member perspective.



This recommendation has been ratified by Welsh Government and will be considered for review every three years.

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