26 April 2019
EMA/231400/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ambrisentan Mylan

ambrisentan

On 26 April 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ambrisentan Mylan, intended for the treatment of pulmonary arterial hypertension (PAH). The applicant for this medicinal product is MYLAN S.A.S.

Ambrisentan Mylan will be available as 5 mg and 10 mg film-coated tablets. The active substance of Ambrisentan Mylan is ambrisentan, an endothelin receptor antagonist (ERA) that is selective for the endothelin type A (ETA) receptor (ATC code: C02KX02). ETA receptor antagonists prevent endothelin-mediated activation of second messenger systems that result in vasoconstriction and smooth muscle cell proliferation.

Ambrisentan Mylan is a generic of Volibris which has been authorised in the EU since 21 April 2008. Studies have demonstrated the satisfactory quality of Ambrisentan Mylan, and its bioequivalence to the reference product Volibris. A question and answer document on generic medicines can be found here.

The full indication is: “treatment of pulmonary arterial hypertension (PAH) in adult patients of WHO Functional Class (FC) II to III, including use in combination treatment (see section 5.1). Efficacy has been shown in idiopathic PAH (IPAH) and in PAH associated with connective tissue disease.” It is proposed that Ambrisentan Mylan should be initiated by a physician experienced in the treatment of PAH.

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.

[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

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