10 November 2016
EMA/CHMP/697437/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Tadalafil Generics

tadalafil

On 10 November 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Tadalafil Generics, intended for the treatment of pulmonary arterial hypertension (PAH) in adults. The applicant for this medicinal product is MYLAN S.A.S.

Tadalafil Generics will be available as 20 mg film-coated tablets. The active substance of Tadalafil Generics is tadalafil (ATC code: G04BE08), a potent and selective inhibitor of cyclic guanosine monophosphate (cGMP) specific phosphodiesterase type 5 (PDE5). Tadalafil increases cGMP within pulmonary vascular smooth muscle cells resulting in relaxation. In patients with pulmonary arterial hypertension this can lead to vasodilation of the pulmonary vascular bed.

Tadalafil Generics is a generic of Adcirca which has been authorised in the EU since 1 October 2016. Studies have demonstrated the satisfactory quality of Tadalafil Generics, and its bioequivalence to Adcirca. A question and answer document on generic medicines can be found here.

The full indication is:

"Treatment of adult patients with pulmonary arterial hypertension (PAH) classified as WHO functional class II and III, to improve exercise capacity (see section 5.1).

Efficacy has been shown in idiopathic PAH (IPAH) and in PAH related to collagen vascular disease."

It is proposed that Tadalafil Generics be prescribed by physicians experienced in the treatment of pulmonary arterial hypertension.

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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