25 April 2025
EMA/CHMP/131389/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Adempas

riociguat

On 25 April 2025, 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 Adempas. The marketing authorisation holder for this medicinal product is Bayer AG.

The CHMP adopted the addition of a new pharmaceutical form, with a new strength (Adempas 0.15 mg/ml granules for oral suspension), along with a change to an existing indication to include treatment of children aged 6 years and older with pulmonary arterial hypertension, as follows:[2]

Pulmonary arterial hypertension (PAH)

Adults

Adempas, as monotherapy or in combination with endothelin receptor antagonists, is indicated for the treatment of adult patients with pulmonary arterial hypertension (PAH) with WHO Functional Class (FC) II to III to improve exercise capacity~~.~~

~~Efficacy has been shown in a PAH population including aetiologies of idiopathic or heritable PAH or PAH associated with connective tissue disease~~ (see section 5.1).

Paediatrics

Adempas is indicated for the treatment of PAH in paediatric patients aged **6 to** less than 18 years ~~of age and body weight ≥ 50 kg~~ with WHO Functional Class (FC) II to III in combination with endothelin receptor antagonists (see section 5.1).

Chronic thromboembolic pulmonary hypertension (CTEPH)

Adempas is indicated for the treatment of adult patients with WHO Functional Class (FC) II to III with

- inoperable CTEPH,

[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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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- persistent or recurrent CTEPH after surgical treatment,

to improve exercise capacity (see section 5.1).

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.