23 July 2026
EMADOC-1829012207-58971
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Riociguat Accord
riociguat

On 23 July 2026 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending the granting of a marketing authorisation for the medicinal product Riociguat Accord, intended for the treatment of chronic thromboembolic pulmonary hypertension (CTEPH) in adults and pulmonary arterial hypertension (PAH) in adults and children.

The applicant for this medicinal product is Accord Healthcare S.L.U.

Riociguat Accord will be available as film-coated tablets (0.5 mg, 1 mg, 1.5 mg, 2 mg and 2.5 mg). The active substance of Riociguat Accord is riociguat, a soluble guanylate cyclase (sGC) stimulator (ATC code: C02KX05). Riociguat has a dual mode of action: it sensitises sGC to endogenous NO (nitric oxide) by stabilising the NO-sGC binding, and directly stimulates sGC independently of NO. Riociguat restores the NO-sGC-cGMP pathway and leads to increased generation of cGMP.

Riociguat Accord is a generic of Adempas, which has been authorised in the EU since 27 March 2014. Studies have demonstrated the satisfactory quality of Riociguat Accord, and its bioequivalence to the reference product Adempas. A question and answer document on generic medicines can be found here.

The full indication is:

> Chronic thromboembolic pulmonary hypertension (CTEPH)
>
> Riociguat Accord is indicated for the treatment of adult patients with WHO Functional Class (FC) II to III with
>
> - inoperable CTEPH,
> - persistent or recurrent CTEPH after surgical treatment,
>
> to improve exercise capacity (see section 5.1).
>
> Pulmonary arterial hypertension (PAH)
>
> Adults
>
> Riociguat Accord, as monotherapy or in combination with endothelin receptor antagonists, is

[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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indicated for the treatment of adult patients with pulmonary arterial hypertension (PAH) with WHO Functional Class (FC) II to III to improve exercise capacity (see section 5.1).

Paediatrics

Riociguat Accord is indicated for the treatment of PAH in paediatric patients aged 6 to less than 18 years with WHO Functional Class (FC) II to III in combination with endothelin receptor antagonists (see section 5.1)

Treatment with Riociguat Accord should only be initiated and monitored by a physician experienced in the treatment of CTEPH or PAH.

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