24 July 2025
EMA/CHMP/225526/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Macitentan Accord

macitentan

On 24 July 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Macitentan Accord, intended for the treatment of adults and children with pulmonary arterial hypertension (PAH). The applicant for this medicinal product is Accord Healthcare S.L.U.

Macitentan Accord will be available as 10 mg film-coated tablets. The active substance of Macitentan Accord is macitentan, an anti-hypertensive for PAH (ATC code: C02KX04). Macitentan is an orally active, endothelin $(ET)_A$ and ET_B receptor antagonist. Macitentan displays high affinity and sustained occupancy of the ET receptors in human pulmonary arterial smooth muscle cells. This prevents endothelin-mediated activation of second messenger systems that result in vasoconstriction and smooth muscle cell proliferation.

Macitentan Accord is a generic of Opsumit, which was authorised in the EU on 20 December 2013. Studies have demonstrated the satisfactory quality of Macitentan Accord, and its bioequivalence to the reference product Opsumit. A question and answer document on generic medicines can be found here.

The full indication is:

> Adults
>
> Macitentan Accord as monotherapy is indicated for the long-term treatment of pulmonary arterial hypertension (PAH) in adult patients of WHO Functional Class (FC) II to III (see section 5.1).
>
> Paediatric population
>
> Macitentan Accord as monotherapy is indicated for the long-term treatment of pulmonary arterial hypertension (PAH) in paediatric patients aged less than 18 years and bodyweight ≥ 40 kg with WHO Functional Class (FC) II to III (see section 5.1).

Treatment with Macitentan Accord should be initiated and monitored by physicians experienced in the treatment of PAH.

[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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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.