



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

24 July 2025  
EMA/CHMP/225527/2025  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (initial authorisation)

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# Macitentan AccordPharma

## 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 AccordPharma, 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 AccordPharma will be available as 10 mg film-coated tablets. The active substance of Macitentan AccordPharma is macitentan, an anti-hypertensive for PAH (ATC code: C02KX04). Macitentan is an orally active, endothelin (ET)<sub>A</sub> and ET<sub>B</sub> receptor antagonist (ATC code: C02KX04). 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 AccordPharma is a generic of Opsumit, which was authorised in the EU since on 20 December 2013. Studies have demonstrated the satisfactory quality of Macitentan AccordPharma, 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 AccordPharma, as monotherapy or in combination, 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

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion



Macitentan AccordPharma, as monotherapy or in combination, is indicated for the long-term treatment of pulmonary arterial hypertension (PAH) in paediatric patients aged less than 18 years and bodyweight  $\geq 40$  kg with WHO Functional Class (FC) II to III (see section 5.1).

Treatment with Macitentan AccordPharma should be initiated and monitored by physicians 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 on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.