



25 July 2024
EMA/CHMP/326580/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Opsumit macitentan

On 25 July 2024, 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 Opsumit. The marketing authorisation holder for this medicinal product is Janssen-Cilag International NV.

The CHMP adopted a new pharmaceutical form, 2.5 mg dispersible tablets, associated with a new indication for the treatment of children from 2 years of age, as follows:

Opsumit, as monotherapy or in combination, is indicated for the long-term treatment of pulmonary arterial hypertension (PAH) in paediatric patients aged 2 years to less than 18 years with WHO Functional Class (FC) II to III (see section 5.1).

The CHMP also adopted an extension to an existing indication for the already authorised 10 mg film-coated tablets to include children weighting at least 40 kg, as follows:²

Adults

Opsumit, 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–

~~Efficacy has been shown in a PAH population including idiopathic and heritable PAH, PAH associated with connective tissue disorders, and PAH associated with corrected simple congenital heart disease (see Section 5.1).~~

Paediatric population

Opsumit, 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).

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



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