25 July 2024
EMA/CHMP/338583/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Yuvanci

macitentan / tadalafil

On 25 July 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Yuvanci, intended for the treatment of pulmonary arterial hypertension (PAH). The applicant for this medicinal product is Janssen-Cilag International NV.

Yuvanci is a fixed dose combination of two active substances and will be available as film-coated tablets containing 10 mg macitentan and either 20 or 40 mg tadalafil. The active substances of Yuvanci are macitentan and tadalafil, antihypertensives for PAH (ATC code: C02KX54). Macitentan is an orally active endothelin receptor antagonist which binds to endothelin receptors on pulmonary arterial smooth muscle cells, thereby reducing vasoconstriction and smooth muscle cell proliferation. Tadalafil is a selective inhibitor of PDE5 which relaxes pulmonary vascular smooth muscle cells and induces the vasodilation of the pulmonary vascular bed.

The benefit of Yuvanci is the reduction in pulmonary vascular resistance at week 16 of treatment in patients with PAH compared with macitentan or tadalafil monotherapy, as observed in a randomised study. Yuvanci was generally well tolerated and had a manageable safety profile, in line with that of the monotherapies. The most common side effects with Yuvanci are anaemia/haemoglobin decrease, oedema/fluid retention and headache.

The full indication is:

> Yuvanci is indicated as substitution therapy for the long-term treatment of pulmonary arterial hypertension (PAH) in adult patients of WHO Functional Class (FC) II to III, who are already treated with the combination of macitentan and tadalafil given concurrently as separate tablets.

Treatment with Yuvanci should be prescribed and supervised 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 in the European public assessment report (EPAR) and

[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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made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.