30 March 2023
EMA/CHMP/130048/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Neparvis

sacubitril / valsartan

On 30 March 2023, 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 Neparvis. The marketing authorisation holder for this medicinal product is Novartis Europharm Limited.

The CHMP adopted the addition of a new pharmaceutical form associated with two new strengths (Neparvis 6 mg/6 mg and 15 mg/16 mg granules in capsule for opening) and a new indication to include treatment of children and adolescents with heart failure. For information, the full indication for granules in capsule for opening will be as follows:

Paediatric heart failure

Neparvis is indicated in children and adolescents aged one year or older for treatment of symptomatic chronic heart failure with left ventricular systolic dysfunction (see section 5.1).

The CHMP also adopted an extension to the existing indication for Neparvis film coated tablets. For information, the full indication for film coated tablets will be as follows:[2]

Adult heart failure

Neparvis is indicated in adult patients for treatment of symptomatic chronic heart failure with reduced ejection fraction (see section 5.1).

Paediatric heart failure

Neparvis is indicated in children and adolescents aged one year or older for treatment of symptomatic chronic heart failure with left ventricular systolic dysfunction (see section 5.1).

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

[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

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(EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

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