14 November 2024
EMA/178674/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

CellCept

mycophenolate mofetil

On 14 November 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 CellCept.

The marketing authorisation holder for this medicinal product is Roche Registration GmbH.

The CHMP adopted an extension to an existing indication to include treatment of children from 1 year of age with CellCept 500 mg film-coated tablets, 250 mg hard capsules and 1 g / 5 ml powder for oral suspension.

For information, the full indication will be as follows:[2]

> CellCept is indicated in combination with ciclosporin and corticosteroids for the prophylaxis of acute transplant rejection in **adult and paediatric (1 to 18 years of age)** patients receiving allogeneic renal, cardiac or hepatic transplants.

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.

[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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