22 July 2010
EMA/CHMP/439259/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Myclausen

Mycophenolate mofetil

On 22 July 2010 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Myclausen, 500 mg, film-coated tablets intended for the prophylaxis of acute transplant rejection in patients receiving allogeneic renal, cardiac or hepatic transplants in combination with ciclosporin and corticosteroids. The applicant for this medicinal product is Herbert J. Passauer GmbH & Co. KG. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Myclausen is mycophenolate mofetil, an immunosuppressive agents (L04AA06). It is a selective, noncompetitive and reversible inhibitor of inosine monophosphate dehydrogenase, resulting in a potent inhibition of guanosine nucleotide synthesis, and therefore exhibits a potent cytostatic effect on lymphocytes.

Myclausen is a generic of CellCept, which has been authorised in the EU since 14 February 1996. Studies have demonstrated the satisfactory quality of Myclausen, and its bioequivalence with the reference product CellCept. A question and answer document on generic medicines can be found here.

A pharmacovigilance plan for Myclausen will be implemented as part of the marketing authorisation.

The approved indication is: “in combination with ciclosporin and corticosteroids for the prophylaxis of acute transplant rejection in patients receiving allogeneic renal, cardiac or hepatic transplants”. It is proposed that treatment with Myclausen should be initiated and maintained by appropriately qualified transplant specialists.

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 will be available in all official European Union languages after 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.

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The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Myclausen and therefore recommends the granting of the marketing authorisation.