25 January 2024
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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): mycophenolate mofetil, mycophenolic acid

Procedure No. EMEA/H/C/PSUSA/00010550/202305

Period covered by the PSUR: 03/05/2021 To: 02/05/2023

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for mycophenolate mofetil, mycophenolic acid, the scientific conclusions of PRAC are as follows:

In view of available data regarding excretion of mycophenolic acid in human milk from the literature, the PRAC considers that excretion of mycophenolic acid in human milk is at least a reasonable possibility. The PRAC concluded that the product information of products containing mycophenolate mofetil, mycophenolic acid should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for mycophenolate mofetil, mycophenolic acid the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing mycophenolate mofetil, mycophenolic acid is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.