10 December 2020
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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/00010550/202005

Period covered by the PSUR: 03/05/2019 - 02/05/2020

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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 the CHMP are as follows:

In view of available data on de novo purine synthesis inhibitors-associated acute inflammatory syndrome from the literature and spontaneous reports, including cases with a close temporal relationship, positive de-challenge and re-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between mycophenolate mofetil, mycophenolic acid and de novo purine synthesis inhibitors-associated acute inflammatory syndrome is established. The PRAC concluded that the product information of products containing mycophenolate mofetil, mycophenolic acid should be amended accordingly.

The CHMP agrees with the scientific conclusions made by the PRAC.

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.