EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 February 2025
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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): cladribine (multiple sclerosis)

Procedure No. EMEA/H/C/PSUSA/00010634/202407

Period covered by the PSUR: 7 July 2023 to 7 July 2024

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for cladribine (multiple sclerosis), the scientific conclusions of PRAC are as follows:

In view of available data on excretion of cladribine in human breastmilk from the literature, the PRAC considers that excretion of cladribine in human milk is at least a reasonable possibility. The PRAC concluded that the product information of products containing cladribine (multiple sclerosis) 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 cladribine (multiple sclerosis) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing cladribine (multiple sclerosis) 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.