17 October 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): cladribine (apart from products with multiple sclerosis indication)

Procedure No. EMEA/H/C/PSUSA/00000787/202402

Period covered by the PSUR:
25/02/2021 To: 25/02/2024

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSURs for cladribine (apart from products with multiple sclerosis indication), 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 (apart from products with multiple sclerosis indication) 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 Authorisations

On the basis of the scientific conclusions for cladribine (apart from products with multiple sclerosis indication) the CHMP is of the opinion that the benefit-risk balance of the medicinal products containing cladribine (apart from products with multiple sclerosis indication) is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisations should be varied.