28 January 2021
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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): hydroxycarbamide (for centrally authorised product only)

Procedure No. EMEA/H/C/PSUSA/00001692/202006

Period covered by the PSUR: 1 July 2019 – 28 June 2020

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for hydroxycarbamide (for centrally authorised product only), the scientific conclusions of CHMP are as follows:

Based on ESCORT-HU results, toxic ranges for neutrophils counts were agreed to be lowered to 1500 cells/ µL (threshold for neutropenia) and intervals for blood cells monitoring at initiation of treatment extended to one month.

Additionally, it was agreed to remove the recommendation for continuous follow-up of the growth of treated children and adolescents. This was based on positive outcome of growth in children treated with hydroxycarbamide from ESCORT-HU and because the caution about "Continuous follow-up of the growth of treated children and adolescents is recommended" was deemed not necessary as it is expected from routine medical practice.

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 hydroxycarbamide (for centrally authorised product only) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing hydroxycarbamide (for centrally authorised product only) 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.