



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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): natalizumab

Procedure No. EMEA/H/C/PSUSA/00002127/202108

Period covered by the PSUR: 07 August 2020 To: 07 August 2021



Scientific conclusions

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

In view of available data the PRAC considers that the physiological drop of haemoglobin cannot solely explain reported anaemia in newborns (in particular as anemia typically occurs 2-3 months after birth) and it is deemed important to monitor and if needed to treat clinical onset of anemia related to natalizumab. The PRAC concluded that the product information of products containing natalizumab 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 natalizumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing natalizumab 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.