25 March 2021
EMA/158932/2021
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/00002127/202008

Period covered by the PSUR: 06/08/2019 To: 06/08/2020

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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 on thrombocytopenia (TCP) and immune (or idiopathic) thrombocytopenic purpura (ITP) from clinical and nonclinical studies, literature sources, post-marketing reports and third-party safety databases, the PRAC considers a causal relationship between natalizumab and thrombocytopenia (TCP) and immune (or idiopathic) thrombocytopenic purpura (ITP) is at least a reasonable possibility. 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.