EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 May 2022
EMA/260516/2022
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): galcanezumab

Procedure No. EMEA/H/C/PSUSA/00010733/202109

Period covered by the PSUR: 28 March 2021 To: 27 September 2021

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 galcanezumab, the scientific conclusions of CHMP are as follows:

In a cumulative review of serious delayed hypersensitivity reactions, the average onset latency of all 44 identified cases was 4.3 days with a range of 24 hours to 29 days. The duration of reaction was reported in 8 cases, in which the average duration of the reactions was 30 days with a range of 3 days to 3 months. The findings confirm that serious hypersensitivity reactions may occur more than 1 day to four weeks after administration and be prolonged in duration. The PRAC Rapporteur concluded that the product information of products containing galcanezumab 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 galcanezumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing galcanezumab 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.