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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): galcanezumab

Procedure No. EMEA/H/C/PSUSA/00010733/202009

Period covered by the PSUR: 28 March 2020 To: 27 September 2020

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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 hypersensitivity events, the information on the time-to-onset confirmed that although many of these events (36.7%) occurred immediately (within 1 day of galcanezumab administration), there were cases where the event occurred 2 to 7 days after initiation of treatment (14.2%), and cases where the event occurred after 4 or more weeks after initiation of the treatment (16.7%). The PRAC concluded that the product information of products containing galcanezumab should be amended accordingly.

Update of section 4.4 of the SmPC to add information that serious hypersensitivity reactions occur mainly within 1 day after galcanezumab administration, however, several cases have occurred also within days or within several weeks. The Package leaflet is updated 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.