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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): fingolimod

Procedure No. EMEA/H/C/PSUSA/00001393/202002

Period covered by the PSUR: 01/03/2019 To: 28/02/2020

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for fingolimod, the scientific conclusions of CHMP are as follows:

Data has been presented on liver injury requiring transplant from spontaneous reports, including one case with a close temporal relationship with fingolimod, and on herpes zoster/herpes simplex infections with fingolimod where 9 new cases of VZV infection with visceral or CNS dissemination and 3 new cases of Herpes simplex infection with visceral or CNS dissemination were reported, adding up to 50 and 20 cumulative cases, respectively. Among these 70 cumulative cases, there were 20 cases of meningoencephalitis, 9 cases of encephalitis and 3 cases of meningitis.

In view of these data, the PRAC agrees that the information should be reflected in the section 4.4 and 4.8 of the SmPC and accordingly in sections 2 and 4 of the PL.

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 fingolimod the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing fingolimod 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.