12 November 2020
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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): alogliptin, alogliptin / metformin, alogliptin / pioglitazone

Procedure No. EMEA/H/C/PSUSA/00010061/202004

Period covered by the PSUR: 14 April 2019 to 14 April 2020

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Scientific conclusions

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

In view of available data on bullous pemphigoid and interstitial nephritis from the literature and spontaneous reports, a close temporal relationship, a positive de-challenge and/or re-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between alogliptin and bullous pemphigoid and interstitial nephritis is at least a reasonable possibility/established. The PRAC concluded that the product information of products containing alogliptin, alogliptin / metformin, alogliptin / pioglitazone 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 alogliptin, alogliptin / metformin, alogliptin / pioglitazone the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing alogliptin, alogliptin / metformin, alogliptin / pioglitazone 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.