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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): linagliptin

Procedure No: EMEA/H/C/PSUSA/00001886/201505

Period covered by the PSUR: 3 May 2014 to 2 May 2015

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Scientific conclusions

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

The evidence on the association between bullous pemphigoid and the use of dipeptidyl peptidase 4 inhibitors including linagliptin has been growing. Twenty three cases of pemphigoid were reported with linagliptin and included eighteen spontaneous cases, literature cases, and one clinical trial case. The three cases reported in literature, of which one showed a clear positive dechallenge, suggest a causal relationship between linagliptin and bullous pemphigoid. Confounding factors do not seem to explain the occurrence of these cases. Based on the cases from literature, the possible mechanism, and further spontaneous reports, the adverse drug reaction “bullous pemphigoid” should be added in section 4.8 of the summary of product characteristics with frequency ‘not known’. The package leaflet should be updated accordingly.

Therefore, in view of the data presented in the reviewed PSUR(s), the PRAC considered that changes to the product information of medicinal products containing linagliptin were warranted.

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