20 November 2014
EMA/CHMP/26417/2015
Committee for Medicinal Products for Human Use (CHMP)

Vipdomet

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: alogliptin / metformin

Procedure No. EMEA/H/C/002654/PSUV/0008

Period covered by the PSUR: 16 October 2013 – 15 April 2014

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Scientific conclusions

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

An analysis of 22 cases of erythema mulitforme reported as serious adverse events for alogliptin containing medicinal products indicated that a relationship between the event and alogliptin seems likely since there were 7 serious cases without confounding factors, and 16 of the 22 serious cases reported a positive dechallenge. Furthermore, exfoliative skin reactions are known for dipeptidyl peptidase-4 (DPP4) inhibitors.

Exfoliative skin disorders in general, including Stevens-Johnson Syndrome (SJS), are already listed in section 4.8 of the SmPCs of Incresync, Vipdomet and Vipidia. However, since erythema multiforme differs in clinical pattern and aetiology from SJS, the MAH is requested to add “erythema multiforme” to the ADR table in section 4.8 of the SmPCs. Furthermore, the wording on hypersensitivity in section 4.4 should be adapted.

Therefore, in view of available data regarding erythema multiforme, the PRAC considered that changes to the product information were warranted. The CHMP agrees with the scientific conclusions made by the PRAC and recommended changes to the SmPC and package leaflet accordingly.

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for Vipdomet, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance alogliptin / metformin is favourable subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation(s) should be varied.