



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

## Incesync

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

International non-proprietary name: alogliptin / pioglitazone

Procedure No. EMEA/H/C/002178/PSUV/0008

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



## **Scientific conclusions**

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

An analysis of 22 cases of erythema multiforme 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 Incesync, 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 Incesync, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance alogliptin / pioglitazone 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.