



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

22 October 2015  
EMA/829798/2015  
Committee for Medicinal Products for Human Use (CHMP)

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

International non-proprietary name: vildagliptin, metformin / vildagliptin

Procedure No. EMEA/H/C/PSUSA/00003113/201502

Period covered by the PSUR: 1 December 2011 to 28 February 2015



During the reporting period concomitant use of ACE inhibitors and vildagliptin resulted in a slightly higher incidence of angioedema in the vildagliptin group versus the comparator group. The incidence of angioedema in patients not taking concomitant ACE inhibitors was the same in both groups. Information regarding the increased risk of angioedema in patients taking ACE inhibitors and vildagliptin is known and already partly reflected in the product information (section 4.8). In line with the Guideline on Summary of Product Characteristics (SmPC) this should also be reflected in section 4.5 of the SmPC.

Therefore, in view of available data regarding vildagliptin and vildagliptin/metformin, the PRAC considered that changes to the product information were warranted.