



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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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: saxagliptin

Procedure No. EMEA/H/C/PSUSA/00002685/201407

Period covered by the PSUR: 31 July 2013 – 30 July 2014



## **Scientific conclusions**

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

Gastrointestinal effects are known for saxagliptin and constipation is a known adverse reaction for other GLP-1 based therapies (sitagliptin, liraglutide). For saxagliptin currently 18 cases of constipation have been reported with a positive de-challenge, including two positive re-challenges which indicate a causal relationship between saxagliptin and constipation. Furthermore, 3 of these 18 cases (1 with positive rechallenge) had a short time to onset (a few days) and no concomitant medication or relevant co-morbidities that could have confounded the development of the constipation. Based on the review of cases of constipation, the PRAC considers constipation an adverse drug reaction with possible causal association with saxagliptin. The product information should therefore be updated to include "constipation" with a frequency "not known" in section 4.8 of the SmPC, and the PL should be updated accordingly.

Therefore, in view of available data regarding constipation, the PRAC considered that changes to the product information were warranted.

The CHMP agrees with the scientific conclusions made by the PRAC.

## **Grounds recommending the variation to the terms of the Marketing Authorisation**

On the basis of the scientific conclusions for saxagliptin the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing saxagliptin is favourable subject to the proposed changes to the product information

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