



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Onglyza

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

International non-proprietary name: saxagliptin

Procedure No.: EMEA/H/C/001039/PSUV/0022

Period covered by the PSUR: 31.07.2012 to 30.07.2013



Scientific conclusions

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

Section 4.8 of the SmPC should be updated by adding 'diarrhoea' as adverse reaction with a frequency of 'common'. The Package leaflet should be updated accordingly. The update of this section is based on two cases from clinical trials with positive de- and rechallenge plus 11 spontaneously reported cases with factors of positive de- and/or rechallenges, and given that it is a known ADR for the other DPP4-inhibitors as well. In regard to the assigned frequency, a total of 106 ADRs of diarrhoea were reported in 2042 patients in a 5-study pooled safety analysis. In a 20-study pooled from Hirshberg et al, 63 ADRs of diarrhoea were reported in 978 patients. Diarrhoea should therefore be ranked under the frequency of 'common ($\geq 1/100$ to $< 1/10$)' according to the guidance provided in the SmPC Guideline.

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 Onglyza, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance 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.