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: repaglinide

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Period covered by the PSUR: 01 January 2012 – 31 December 2014

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Scientific conclusions

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

Scientific conclusions and grounds for variation to the terms of the marketing authorisations

A drug interaction study in healthy volunteers showed that there is a considerable pharmacokinetic (PK) and a mild pharmacodynamic interaction between clopidogrel and repaglinide. No new safety information on a drug interaction between clopidogrel and repaglinide could be identified from spontaneous reports. However, based on the above mentioned study results and the experience with other CYP2C8 inhibitors, it is considered that the observed interaction between repaglinide and clopidogrel is possibly clinically relevant and therefore the product information of repaglinide should be updated to add information on the effects of the co-administration clopidogrel with repaglinide.

Therefore, in view of available data regarding the drug interaction with clopidogrel, 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 repaglinide the CHMP is of the opinion that the benefit-risk balance of the medicinal products containing repaglinide is favourable subject to the proposed changes to the product information

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