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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: orlistat

Procedure No. EMEA/H/C/PSUSA/00002220/201502

Period covered by the PSUR: 8 February 2014 – 7 February 2015

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Scientific conclusions

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

Based on cumulative reviews a total of 7 cases have been reported demonstrating a likely interaction between orlistat and benzodiazepines. This data is sufficient to postulate that an interaction exists and product information has been updated accordingly.

In addition, a total of 169 cases have been associated with an antidepressant and 27 cases with antipsychotics, 48,5% and 55,5% respectively, reported lack of efficacy while receiving orlistat 60 mg in association with antidepressants, antipsychotics and lithium. This data is sufficient to postulate that an interaction exists. This interaction is already listed for orlistat 120 mg however not for orlistat 60 mg, therefore the product information for orlistat 60 mg has been updated accordingly.

Therefore, in view of available data regarding orlistat, 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 orlistat the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing orlistat 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.