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: zaleplon

Procedure No. EMEA/H/C/PSUSA/00003140/201407

Period covered by the PSUR: 16 July 2011 – 15 July 2014

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Scientific conclusions

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

Literature articles regarding next day effects on driving and mental alertness were published during the reporting period which examined these effects with zaleplon and other agents of the class. While there were no significant findings in relation to zaleplon, a small number of cases have been reported in the post-marketing setting, although mostly in combination with other CNS depressant agents and at doses greater than 10mg.

Warnings already exist in the zaleplon product information however based on the available information the PRAC considered it prudent within this procedure to strengthen the wording in SmPC and PL to ensure clear information is available for patients and healthcare professionals given the potentially serious consequences of next day psychomotor impairment.

Therefore, in view of available data regarding next day effects on driving and mental alertness, 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 zaleplon the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing zaleplon is favourable subject to the proposed changes to the product information

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