EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA/294682/2014
Committee for Medicinal Products for Human Use (CHMP)

Ketek

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

International non-proprietary name: telithromycin

Procedure No. EMEA/H/C/000354/PSUV/0060

Period covered by the PSUR: 10 July 2012 to 9 July 2013

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Scientific conclusions

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

The assessment of this PSUR revealed that the use of telithromycin was still associated with a considerable number of visual adverse events such as blurred vision, visual impairment, diplopia and accommodation disorders, that may be both severe and of sudden onset.

The PRAC agreed to recommend that the paragraphs in sections 4.4 and 4.8 of the SmPC referring to visual disturbances should be made clearer concerning the risk for severe and sudden visual reactions.

In addition, the PRAC recommended the addition of a sentence concerning the interaction between telithromycin and sotalol in section 4.5 of the SmPC, and the addition of gamma-glutamyltransferase increase to the table in section 4.8, within the SOC 'Hepatobiliary disorders', grouped under 'Increase in liver enzymes' and with a frequency of 'common'.

The PL was amended accordingly.

Based on the review on data on safety and efficacy, the benefit–risk balance of telithromycin in the approved indications remains favourable.

The product has been approved since 2001. The safety profile is presently considered to be more established and it is therefore recommended that the PSUR periodicity should be changed from 1 year to 2 years.

The next PSUR should be submitted in accordance with the requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c (7) of Directive 2001/83/EC and published on the European medicines web-portal.

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 Ketek, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance telithromycin is favourable subject to the proposed changes to the product information.

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