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Committee for Medicinal Products for Human Use (CHMP)

Prezista

Darunavir

Procedure No. EMEA/H/C/000707/PSUV/059

Scientific conclusions and grounds recommending the variation to the terms of the Marketing Authorisation

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Scientific conclusions

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

This Periodic Safety Update Report for darunavir summarises the safety data obtained by the MAH from worldwide sources for the reporting period of 24 December 2011 to 23 December 2012.

The review of the efficacy data received during the reporting period did not identify any relevant new information that had an impact on the known efficacy or effectiveness profile for any of the authorised indications.

The risks as defined in the RMP have not been changed in general. However, cumulatively 12 cases of Drug Rash With Eosinophilia And Systemic Symptoms (DRESS) have been reported, of which 1 fatal case. Eleven cases were from post marketing experience and 1 from a clinical study. Six cases were presented and discussed in this PSUR covering the period from 24 December 2011 to 23 December 2012.

In two of the 6 cases presented and discussed in this PSUR a relationship with darunavir is not very likely. In the other cases, based on time to onset, clinical picture (prolonged course) and the assessment of the reporters, DRESS and darunavir (possibly together with an interaction of darunavir and raltegravir) should be regarded as least possibly related.

The fatal case concerns an interaction of darunavir and raltegravir and a contribution of darunavir cannot be excluded.

The sections 4.4 and 4.8 of the SmPC have been updated with DRESS. The frequency class for DRESS is rare. The PIL has been updated accordingly.

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

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