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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): artenimol / piperaquine tetraphosphate

Procedure No. EMEA/H/C/PSUSA/00001069/201910

Period covered by the PSUR: 28 April 2018 To: 27 October 2019

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for artenimol / piperaquine tetraphosphate, the scientific conclusions of CHMP are as follows:

Based on evidence from literature as regards the significant increase of resistance against artemisinins and/or piperaquine based therapies in Plasmodium falciparum, the PRAC considered that a change in the product information of products containing artenimol/piperaquine to adequately reflect this risk, taking into account recent findings in terms of frequencies which might change the benefit of Eurartesim in certain regions, is needed.

Furthermore, the PRAC considered based on a literature article that an update of section 4.5 of the SmPC with the drug-drug interaction between efavirenz and artenimol / piperaquine tetraphosphate was warranted. In addition, this section was further updated to reflect currently authorised antiretroviral medicines. The package leaflet is updated accordingly.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for artenimol / piperaquine tetraphosphate the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing artenimol / piperaquine tetraphosphate is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.