22 June 2023
EMA/392409/2023
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/00001069/202210

Period covered by the PSUR:
27/10/2019 To: 27/10/2022

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact Telephone +31 (0)88 781 6000 An agency of the European Union

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:

In view of available data on hepatocellular injury from spontaneous reports in adults including in some cases a close temporal relationship, a positive de-challenge, the PRAC considers a causal relationship between artenimol / piperaquine tetraphosphate and hepatocellular injury is at least a reasonable possibility. The PRAC concluded that the product information of products containing artenimol / piperaquine tetraphosphate should be amended 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.