



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

20 July 2023  
EMA/371965/2023  
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): artesunate

Procedure No. EMEA/H/C/PSUSA/00010958/202212

Period covered by the PSUR:  
22/06/2022 To: 22/12/2022



## **Scientific conclusions**

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

In view of available data on risk(s) of "immune haemolytic anaemia" and "Electrocardiogram QT prolonged" from the literature and spontaneous reports including in some cases a close temporal relationship and in view of a plausible mechanism of action, the PRAC considers that a causal relationship between artesunate (IV) and "immune haemolytic anaemia" as well as for "Electrocardiogram QT prolonged" is at least a reasonable possibility. The PRAC concluded that the product information of products containing artesunate (IV) 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 artesunate the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing artesunate 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.