19 June 2025
EMADOC-1700519818-2431478
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): stiripentol

Procedure No. PSUSA/00002789/202411

Period covered by the PSUR: 1 year to 04 November 2024

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 stiripentol, the scientific conclusions of PRAC are as follows:

In view of available data on risk from clinical trial(s) and spontaneous reports, the PRAC considers a causal relationship between stiripentol and pneumonia is at least a reasonable possibility. The PRAC concluded that the product information of products containing stiripentol should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

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

On the basis of the scientific conclusions for stiripentol the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing stiripentol 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.