14 October 2021
EMA/17065/2022
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): nalmefene

Procedure No. EMEA/H/C/PSUSA/00010120/202102

Period covered by the PSUR: 24 February 2018 To: 24 February 2021

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 nalmefene, the scientific conclusions of CHMP are as follows:

In view of available data on 'visual impairment' from clinical trial(s) and spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge, the PRAC Rapporteur considers a causal relationship between nalmefene and 'visual impairment' is at least a reasonable possibility. The PRAC Rapporteur concluded that the product information of products containing nalmefene 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 nalmefene the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing nalmefene 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.