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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): nalmefene

Procedure No. EMEA/H/C/PSUSA/00010120/201602

Period covered by the PSUR: 25 Feb 2015 to 24 Feb 2016

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Scientific conclusions

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

The concomitant use of nalmefene and opioids is contraindicated as per section 4.3 of the Summary of Product Characteristics. In spite of the contraindication, it still remains an ongoing safety issue. Cumulatively, 88 cases were identified concerning the contraindicated use of nalmefene in patients concurrently taking a potent opioid. Of these, 69 cases concerned concomitant use of methadone and/or buprenorphine. To further minimize this problem and highlight the contraindication to patients, the Package Leaflet should be updated with methadone and buprenorphine as examples of opioid substances that are contraindicated.

Therefore, in view of the data presented in the reviewed PSUR(s), the PRAC considered that changes to the product information of medicinal products containing nalmefene were warranted.

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.