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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/00010120/201702

Period covered by the PSUR: 25 Feb 2016 – 24 Feb 2017

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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:

A total of 35 cases of myalgia were cumulatively reported from post-marketing sources, including ten serious and 25 non-serious cases. De-challenge was positive in 20 of these cases. The causality was assessed as probable in one case due to a positive re-challenge and as possible in 16 cases due to the temporal relationship. In six cases, causality was assessed as unlikely and 12 cases could not be evaluated due to insufficient information. In the phase III Otsuka study, the incidence of myalgia was increased in the nalmefene groups as compared to the placebo group (20 mg nalmefene: 1.6 %; 10 mg nalmefene: 1.1 %; placebo: 0.4 %). Overall, myalgia was considered an adverse drug reaction with a possible causal relationship and was assigned the frequency category “unknown”.

Ten cases of suicide/ self-injury were reported from post-marketing sources during the PSUR-reporting period. The majority of these cases either reported strong confounding factors including medical history of depression, anxiety, psychosis and drug abuse or lacked important information allowing for an adequate causality assessment. In view of the serious nature of suicidality, a warning on the risk of suicidal ideation in alcohol and substance abusers was considered of benefit to the prescribers.

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.