20 September 2018
EMA/856642/2018
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/00010120/201802

Period covered by the PSUR: 25 Feb 2017 - 24 Feb 2018

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

Scientific conclusions

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

Cases of “priapism” have been reported in nalmefene treated patients. Priapism is defined as an erection lasting more than 4 hours, and is divided into ischemic (painful) and non-ischemic (painless) type. Priapism is a condition demanding medical attention. Due to the number of cases of positive dechallenge (one erection increased, six priapism, one spontaneous erection) and some potential cases of positive rechallenge and due to the nature of the symptoms, where a certain amount of underreporting is to be expected, there is a potential causal relationship between priapism and nalmefene. Hence, Priapism should be added as a new adverse drug reaction with a frequency ‘unknown’ in section 4.8 of the SmPC and section 4 of the Package Leaflet.

Cumulatively, 305 adverse drug reactions in 264 cases in the system organ class skin and subcutaneous tissue disorders have been reported from post-marketing sources. Of those, 66 adverse drug reactions in 56 cases were assessed as possibly or probably related to nalmefene. Reviewing in more detail the skin and subcutaneous tissue disorders, it is concluded that a causal relationship between nalmefene and the reactions angioedema, urticaria, pruritus, rash, and erythema cannot be excluded. Hence, these terms should be added as new adverse drug reactions with a frequency ‘unknown’ in section 4.8 of the SmPC and section 4 of the Package Leaflet.

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.