EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 March 2015
EMA/CHMP/268466/2015
Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: nalmefene

Procedure No. EMEA/H/C/PSUSA/00010120/201408

Period covered by the PSUR: 25 February 2014 – 24 August 2014

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 for nalmefene, the scientific conclusions of CHMP are as follows:

During the reporting period 12 cases of newly identified withdrawal syndrome following concomitant utilisation with buprenorphine and methadone have been identified. Currently nalmefene is contraindicated in patients taking opioid analgesics, therefore the contraindication should be updated to include patients taking opioids for substitution therapy with opioid agonists (e.g. methadone) or partial agonists (e.g. buprenorphine).

Therefore, in view of available data regarding nalmefene, the PRAC considered that changes to the product information were warranted.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds recommending the variation to the terms of the Marketing Authorisation

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 favourable subject to the proposed changes to the product information

The CHMP recommends that the terms of the Marketing Authorisation(s) should be varied.