30 May 2024
EMA/243985/2024
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): buprenorphine / naloxone

Procedure No. EMEA/H/C/PSUSA/00002113/202309

Period covered by the PSUR: 25 September 2019 To: 25 September 2023

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Scientific conclusions

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

In view of available data on the interaction between opioids and gabapentinoids from the literature, in view of a plausible mechanism of action and taking into account the existing warnings in product information of other opioid containing products, the PRAC considers a causal relationship between buprenorphine/naloxone and interaction with gabapentinoids is at least a reasonable possibility. The PRAC concluded that the product information of products containing buprenorphine/naloxone should be amended accordingly.

In view of available data on dental caries from the literature and spontaneous reports including in some cases a close temporal relationship and in view of a plausible mechanism of action, the PRAC considers a causal relationship between buprenorphine/naloxone and dental caries is at least a reasonable possibility. The PRAC concluded that the product information of products containing buprenorphine/naloxone should be amended accordingly.

In view of available data on paediatric intoxication and fatal outcomes from the literature and spontaneous reports and in view of a plausible mechanism of action, the PRAC considers a causal relationship between buprenorphine/naloxone and paediatric intoxication and fatal outcomes is at least a reasonable possibility. The PRAC concluded that the package leaflet of products containing buprenorphine/naloxone should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for buprenorphine / naloxone the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing buprenorphine / naloxone 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.