EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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): buprenorphine (all formulations except implants)

Procedure No. EMEA/H/C/PSUSA/00000459/202309

Period covered by the PSUR:
30/09/2020 To: 30/09/2023

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Scientific conclusions and grounds for variation to the terms of the marketing authorisations

In view of available data from spontaneous sources and literature on the interactions between opioids and gabapentinoids as well as anticholinergics, and taking into account the existing warnings in product informations of other opioid containing products, the PRAC concluded that the product information of products containing buprenorphine (all formulations except implants) should be amended accordingly.

In view of available data from the literature and spontaneous reports on risks of paediatric intoxication, including some fatal cases, the PRAC concluded that the package leaflet of products containing buprenorphine (all formulations except implants) should be amended accordingly (except those for which take-home use by patients is not allowed as per the instructions of the product information).

In view of available data on the risk of medication errors related to a wrong route of administration (e.g. intradermally, intramuscularly, intravenously), the PRAC concluded that the product information of products containing buprenorphine (all formulations except implants) for subcutaneous injection only, should be amended accordingly.

In view of available data on the risk of drug dependency/drug abuse from post-marketing case reports and literature data, and taking into account the existing warnings in product information of other opioid containing products, the PRAC concluded that the product information of products containing buprenorphine (all formulations except implants) should be updated to reinforce the labelling on the risk of drug dependency/drug abuse by adding negative consequences of opioid use disorder and risk factors identified in accordance with wordings already implemented for other opioids.

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 (all formulations except implants) for oromucosal use and dental caries is at least a reasonable possibility. The PRAC concluded that the product information of products containing buprenorphine (all formulations except implants) for oromucosal use should be amended accordingly.