25 January 2024
EMA/57780/2024
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): fentanyl (transmucosal route of administration)

Procedure No. EMEA/H/C/PSUSA/00001369/202304

Period covered by the PSUR: 30/04/2020 to 30/04/2023

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Scientific conclusions

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

In view of literature reports, spontaneous reports and previous actions taken for other opioid products (e.g. fentanyl transdermal patches, solution for injection), the PRAC considers that further information regarding Opioid Use Disorder (OUD) should be communicated to the prescribers and patients. The PRAC concluded that the product information of products containing fentanyl (transmucosal route of administration) should be amended accordingly.

In view of literature reports, spontaneous reports and previous actions taken for other opioid products (e.g. fentanyl transdermal patches, solution for injection), the PRAC considers that further information regarding the storage in a safe and secure place should be provided in the product information. The PRAC concluded that the product information of products containing fentanyl (transmucosal route of administration) should be amended accordingly.

In view of available data on toxic leukoencephalopathy in a context of overdose from the literature and spontaneous reports including cases with at least a reasonable possibility for a causal relationship with fentanyl overdose, the PRAC Rapporteur concluded that the product information of products containing fentanyl (transmucosal route of administration) 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 fentanyl (transmucosal route of administration) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing fentanyl (transmucosal route of administration) 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.