COMMUNICATION

COM-2022-009

20 JANUARY 2022

URGENT PLEASE REVIEW

Safety Notification

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate you with the latest up-to-date drug safety information.

U.S. Food & Drug Administration Publication Date:

01/12/2022

Drug Indication:

Buprenorphine for the treatment of opioid use disorder (OUD) and pain

Safety Topic:

FDA warns about dental problems with buprenorphine medicines dissolved in the mouth to treat opioid use disorder and pain

Dental Problems with Buprenorphine

It is for this reason that we are notifying you that on 01/12/2022 the U.S. Food and Drug Administration published a safety communication for the following product(s): Buprenorphine.

Reason for Communication:

The U.S. FDA is warning that dental problems have been reported with medicines containing buprenorphine that are dissolved in the mouth. The dental problems, including tooth decay, cavities, oral infections, and loss of teeth, can be serious and have been reported even in patients with no history of dental issues.

The FDA is requiring a new warning about the risk of dental problems be added to the prescribing information and the patient Medication Guide for all buprenorphine-containing medicines dissolved in the mouth. It will include strategies to maintain or improve oral health while undergoing treatment with these medications. Despite these risks, buprenorphine is an important treatment option for OUD and pain, and the benefits of these medicines clearly outweigh the risks.

Pharmacy Required Action:

Advise patients that they should not discontinue using the medication without contacting their healthcare provider. Patients experiencing any problem while taking or using this product must contact their physician

Assess whether the potential benefits of continuing the drug outweigh the potential risks highlighted in this safety communication. Counsel patients about the potential for dental problems and the importance of taking extra steps after the medicine has completely dissolved, including to gently rinse their teeth and gums with water and then swallow. Patients should be advised to wait at least 1 hour before brushing their teeth.

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

Complete and submit the MedWatch Online Voluntary Reporting Form online.

Download FDA Form 3500 or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

Additional information can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252- Clinical Department. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

PharmPix Drug Safety Communication Number COM-2022-009 January 2022

pharmpix
POWERED BY ONEARK

urac
ACCREDITED
Pharmacy Benefit Management
Expires 12/01/2022

REFERENCES:

1. U.S. Food and Drug Administration. (2021). FDA warns about dental problems with buprenorphine medicines dissolved in the mouth to treat opioid use disorder and pain. https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-dental-problems-buprenorphine-medicines-dissolved-mouth-treat-opioid-use-disorder
2. MedWatch: The FDA Safety Information and Adverse Event Reporting Program. https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda

2 Street 1, Suite 500
Guaynabo, PR 00968

Tel. 787.522.5252
Fax 866.912.2830

www.pharmpix.com
FRM-CL-000127-000

CLINICAL PEARLS
BY PHARMPIX