



SAFETY ALERT

DRAP SAFETY ALERT NO. 31

Safety Alert Risk of dental problems with orally dissolved Buprenorphine

Date: 10th of April, 2023.

Target Audience:

- Manufacturers and importers of Buprenorphine medicines;
- Healthcare Professionals; and
- Patients, consumers or caregivers.

Background:

The United States Food and Drug Administration (US-FDA) on 12th of January, 2022 through a drug safety communication warned that dental problems have been reported with medicines containing buprenorphine that are dissolved in the mouth. Dental problems, including tooth decay, cavities, oral infections, and loss of teeth have been reported, even in patients with no prior history of dental issues. The buprenorphine medicines that are associated with dental problems are tablets and films that are dissolved under the tongue or placed against the inside of the cheek. There are also buprenorphine products for pain and opioid use disorder (OUD) delivered by other routes such as a skin patch and injection, but FDA has not identified a concern for dental health related to these other forms.

Action in Pakistan:

Accordingly, the case of risk of dental problems with orally dissolved Buprenorphine was discussed in the 2nd meeting of the Pharmacovigilance Risk Assessment Expert Committee (PRAEC) of the National Pharmacovigilance Centre (NPC), Division of Pharmacy Services, Drug Regulatory Authority of Pakistan (DRAP) which after detailed deliberation and discussion decided





as per Rule 10 (1) (h) (iv) of Pharmacovigilance Rules, 2022 to update the prescribing information/safety specification of buprenorphine medicines that are dissolved in the mouth by including information related to the risk of dental issues, pre-prescribing assessment of patients and guidelines of taking extra steps after use in the warning and precaution sections.

Therapeutic Goods Affected.

Name: **Buprenorphine medicines that are orally dissolved.**

Buprenorphine is an opioid used to treat opioid use disorder (misuse of prescribed opioid medications) and pain. The comprehensive approach of buprenorphine combined with counselling and other behavioural therapies is often one of the most effective ways to treat OUD. At proper doses, buprenorphine also decreases the pleasurable effects of other opioids, making misuse of them less appealing.

Advice for patients.

Patients are advised to continue taking buprenorphine medicine as prescribed and not to stop it suddenly as it could lead to serious consequences including withdrawal symptoms. Patients are also advised to take extra steps to reduce the risk of serious dental problems such as rinsing their mouth with water and waiting at least 1 hour before brushing their teeth after buprenorphine medicines are dissolved to avoid damage to their teeth.

Advice for healthcare professionals.

Healthcare professionals are advised to be aware that the benefits of buprenorphine medicines still clearly outweigh the risks in treating OUD patients and should ask patients about their oral health history before prescribing treatment with the transmucosal/oral buprenorphine medicines. Healthcare professionals should also 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 and to wait at least 1 hour before brushing their teeth.





Guidelines for reporting Adverse Drug Reactions (ADRs):

Both healthcare professionals and patients are requested to report any suspected adverse drug reaction (ADRs) with oral buprenorphine medicines to the National Pharmacovigilance Centre, Drug Regulatory Authority of Pakistan through the [Med Vigilance E-Reporting system](#) available on the DRAP website.

Similarly, ADRs can also be reported through MedSafety App which is available for download from the [App Store](#) (for iOS devices) and [Google Play](#) (for Android devices).

References:

1. [Minutes of 2nd meeting of Pharmacovigilance Risk Assessment Expert Committee.](#)

