

## Buprenorphine-containing transmucosal drugs – Safety update

- On January 12, 2022, the [FDA announced](#) a 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.
- The buprenorphine medicines that are associated with dental problems are tablets and films dissolved under the tongue or placed against the inside of the cheek and include generics and brand products and combination products with naloxone such as [Belbuca®](#), [Bunavail® \(buprenorphine/naloxone\)](#), [Cassipa® \(buprenorphine/naloxone\)](#), [Suboxone® \(buprenorphine/naloxone\)](#), [Subutex®](#), and [Zubsolv® \(buprenorphine/naloxone\)](#).
  - Belbuca is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.
  - Bunavail, Cassipa, Suboxone, Subutex and Zubsolv are indicated for treatment of opioid dependence.
- 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.
- A search of the [FDA Adverse Event Reporting System \(FAERS\) database](#) and the medical literature through December 31, 2018, identified 305 cases of dental adverse events reported with transmucosal buprenorphine use. A total of 26 cases described severe dental issues in patients with no reported prior history of dental problems. Although most of the cases were in patients using transmucosal buprenorphine products for OUD, there was a subset of 28 patients who experienced severe dental adverse events while receiving pain-only indicated products.
  - Many cases reported a combination of dental decay, tooth loss, and tooth fractures in numerous teeth.
  - Of the 305 cases, 151 reported the treatment for the adverse event, with tooth extraction/removal as the most common, which was reported in 71 cases. Other treatments included root canal, dental surgery, and other restorative procedures such as crowns and implants.
- Patients should not suddenly stop taking buprenorphine medicines without first talking to their health care professional as it could lead to serious consequences, including relapse to opioid misuse or abuse that could result in overdose and death. The benefits of buprenorphine medicines clearly outweigh the risks.

- Healthcare professionals should refer patients to a dentist as soon as possible after starting transmucosal buprenorphine for a baseline dental evaluation, dental caries risk assessment and preventive plan, and encourage them to have regular dental checkups while taking the medicine.



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