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# Orally Dissolving Buprenorphine Tied to Severe Tooth Decay, FDA Warns

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Orally dissolving medications containing buprenorphine are linked to severe dental problems, including total tooth loss, the US Food and Drug Administration (FDA) warns in a safety communication.

The oral side effects of these medications, which are used to treat opioid use disorder (OUD) and pain, include cavities/tooth decay, including rampant caries; dental abscesses/infection; tooth erosion; fillings falling out; and, in some cases, total tooth loss.

Multiple cases have been reported even in patients with no history of dental problems.

The FDA is adding a warning about the risk of dental problems to the prescribing information and the patient medication guide for all buprenorphine-containing medicines dissolved in the mouth.

The FDA emphasizes, however, that buprenorphine remains "an important treatment option for OUD and pain, and the benefits of these medicines clearly outweigh the risks."

## More Than 300 Reported Cases

Buprenorphine was approved in 2002 as a sublingual tablet, and in 2015 as a film to be placed inside the cheek to treat pain. Both delivery methods have been associated with dental problems.

Since buprenorphine was approved, the FDA has identified 305 cases of dental problems associated with orally dissolving buprenorphine, including 131 classified as serious.

There may be other cases, the FDA says, as these represents only cases reported to the FDA or published in the medical literature.

The average age of the patients who developed dental problems while taking buprenorphine is 42 years, but those as young as 18 years old were also affected.

Most cases occurred in patients using the medicines for OUD; however, 28 cases of dental problems occurred in patients using it to treat pain.

In 26 cases, patients had no prior history of dental problems. Some dental problems developed as soon as 2 weeks after treatment began; the median time to diagnosis was about 2 years after starting treatment.

Among all 305 cases reported, 113 involved two or more teeth.

The most common treatment for the dental problems was tooth extraction/removal, which was reported in 71 cases. Other cases required root canals, dental surgery, and other procedures such as crowns and implants.

## Recommendations

The FDA says healthcare providers should counsel patients that severe and extensive tooth decay, tooth loss, and tooth fracture have been reported with the use of transmucosal buprenorphine-containing medicines and emphasize the importance of visiting their dentist to closely monitor their teeth.

Patients should be counseled to continue taking buprenorphine medications as prescribed and not stop suddenly without first talking to their healthcare provider as this could lead to serious consequences, including relapse, misuse or abuse of other opioids, overdose, and death.

Patients are also being advised to take extra steps to help lessen the risk of serious dental problems.

Patients should also be educated on strategies to maintain or improve oral health while taking transmucosal buprenorphine medicines.

After the medicine is completely dissolved, the patient should take a large sip of water, swish it gently around the teeth and gums, swallow, and wait at least 1 hour before brushing their teeth, the FDA advises. This will allow time for the mouth to gradually return to oral homeostasis and avoid any mechanical damage that may occur due to brushing.

The FDA also advises that patients tell their provider about any history of tooth problems, including cavities, and schedule a dentist visit soon after starting the medicine.

Dental problems related to transmucosal buprenorphine-containing medicines should be reported to the FDA's MedWatch program.

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