Buprenorphine: Drug Safety Communication - FDA warns about dental problems with buprenorphine medicines dissolved in the mouth to treat opioid use disorder and pain

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AUDIENCE: Dentistry, Anesthesiology, Patient, Health Professional, Pharmacy

ISSUE: The 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. Despite these risks, buprenorphine is an important treatment option for opioid use disorder (OUD) and pain, and the benefits of these medicines clearly outweigh the risks.

The FDA is requiring a new warning about the risk of dental problems be added to the prescribing information and the patient Medication Guide (https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=medguide.page) for all buprenorphine-containing medicines dissolved in the mouth.

BACKGROUND: Buprenorphine was approved in 2002 as a tablet to be administered under the tongue to treat OUD. In 2015, buprenorphine was approved as a film to be placed inside the cheek to treat pain. 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.

RECOMMENDATIONS:

Patients

- Continue taking your buprenorphine medicine as prescribed; do not suddenly stop taking it without first talking to your health care professional as it could lead to serious consequences. Suddenly stopping these medicines could cause you to become sick with withdrawal symptoms because your body has become used to the buprenorphine medicine, or to relapse to opioid misuse that could result in overdose and death.

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- Patients using buprenorphine medicines dissolved in the mouth should take extra steps to help lessen the risk of serious dental problems. After the medicine is completely dissolved, take a large sip of water, swish it gently around your teeth and gums, and swallow. You should wait at least 1 hour before brushing your teeth to avoid damage to your teeth and give your mouth a chance to return to its natural state.
- Inform your health care professional if you have a history of tooth problems, including cavities. Schedule a dentist visit soon after starting this medicine and inform your dentist that you are taking buprenorphine, and schedule regular dental checkups while taking this medicine. Your dentist can customize a tooth decay prevention plan for you. Notify both your health care professional and your dentist immediately if you experience any problems with your teeth or gums.

Health Professionals

- Health care professionals should be aware the benefits of buprenorphine medicines clearly outweigh the risks and are an important tool to treat OUD. When combined with counseling and other behavioral therapies, this comprehensive medication-assisted treatment (https://www.samhsa.gov/medication-assisted-treatment) approach is often the most effective way for treating OUD, and can help sustain recovery and prevent or reduce opioid overdose.
- Ask patients about their oral health history prior to prescribing treatment with a transmucosal buprenorphine medicine. These serious dental problems have been reported even in patients with no history of dental issues, so refer them to a dentist as soon as possible after starting transmucosal buprenorphine. 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. Dentists treating someone taking a transmucosal buprenorphine product should perform a baseline dental evaluation and caries risk assessment, establish a dental caries preventive plan, and encourage regular dental checkups.

Health professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report online (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm)
- Download form (https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on form or submit by fax to 1-800-FDA-0178

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