

FENTORA

FOR HEALTHCARE PROFESSIONALS

Important Safety Information

FENTORA can cause life-threatening breathing problems.

Do not use **FENTORA** unless you are regularly using another opioid medication around-the-clock for your cancer pain and your body is used to these medicines (this means you are opioid tolerant). You can ask your healthcare provider if you are opioid tolerant. Keep **FENTORA** in a safe place away from children.

[Read More Important Safety Information >>](#)

UNDERSTANDING BTP

FENTORA & BTP

TAKING FENTORA

SAVINGS & SUPPORT

Learn how **FENTORA** (fentanyl buccal tablet) CII may help you with breakthrough pain in cancer^{1,2}

FENTORA is a prescription medicine that contains fentanyl and is used to manage breakthrough pain in adults with cancer who are already routinely taking other opioid pain medicines around-the-clock for cancer pain. **FENTORA** is only available through the TIRF REMS Access program.



A booklet to help you better understand breakthrough pain in cancer and how **FENTORA** can help manage it.

Copay and reimbursement, simplified



First month FREE*



\$5 copays*



Dedicated reimbursement support
Call 1-877-4FENTORA (1-877-433-6867)
(Open Monday - Friday 8 am - 7 pm CST)

*In accordance with the [Terms and Limitations](#) >

FENTORA provides relief that generally matches the pattern of breakthrough pain in opioid-tolerant adults with cancer.^{1,2}

FENTORA is an oral tablet placed inside your mouth to dissolve.²

IMPORTANT SAFETY INFORMATION

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Do not use **FENTORA** unless you are regularly using another opioid pain medicine around-the-clock for your cancer pain and your body is used to these medicines (this means you are opioid tolerant). You can ask your healthcare provider if you are opioid tolerant.

Keep **FENTORA** in a safe place away from children.

Get emergency help **IMMEDIATELY** if:

- A child takes **FENTORA**. **FENTORA** can cause an overdose and death in any child who takes it
- An adult who has not been prescribed **FENTORA** uses it
- An adult who is not already taking opioids around-the-clock uses **FENTORA**

These are medical emergencies that can cause death. If possible, try to remove **FENTORA** from the mouth.

What important information should I know about **FENTORA**?

FENTORA can cause life-threatening breathing problems.

- Use **FENTORA** exactly as prescribed by your healthcare provider
 - DO NOT use more than 2 doses of **FENTORA** for each episode of breakthrough cancer pain
 - Wait at least 4 hours before treating a new episode of breakthrough cancer pain with **FENTORA**
- Do not switch from **FENTORA** to other medicines that contain fentanyl or change your **FENTORA** dose without talking with your healthcare provider
- **Never give FENTORA to anyone else**, even if they have the same symptoms you have. It may harm them or even cause death and is against the law. Keep **FENTORA** in a safe place

FENTORA is available only through a program called the Transmucosal Immediate-Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS) Access program. To receive **FENTORA**, you must talk to your healthcare provider about the benefits and risks of **FENTORA**, agree to all of the instructions, and sign the Patient-Prescriber Agreement Form.

Who should not use **FENTORA**?

Do not use **FENTORA**:

- If you are not opioid tolerant. Opioid tolerant means that you are already taking other opioid pain medicines around-the-clock for your cancer pain, and your body is used to these medicines
- For short-term pain that you would expect to go away in a few days, such as pain after surgery, headaches or migraine, and/or dental pain
- If you are allergic to any of the ingredients in *FENTORA*

What should I tell my healthcare provider before using *FENTORA*?

Tell your healthcare provider about all the medicines you take, including prescription medicines, vitamins, and herbal supplements. Some medicines may cause serious or life-threatening side effects when taken with *FENTORA*.

- Do not take any medicine while using *FENTORA* until you have talked to your healthcare provider. Your healthcare provider will tell you if it is okay to take other medicines while you are using *FENTORA*
- Be very careful about taking other medicines that may make you sleepy, such as other pain medicines, antidepressant medicines, sleeping pills, anti-anxiety medicines, antihistamines, or tranquilizers

What should I avoid while using *FENTORA*?

- Do not drive, operate heavy machinery, or do other dangerous activities until you and your healthcare provider know how *FENTORA* affects you
- Do not drink alcohol while using *FENTORA*. It can increase the chance of dangerous side effects

What are possible side effects of *FENTORA*?

FENTORA can cause serious side effects, including:

1. **Breathing problems that can become life-threatening.**
Stop taking *FENTORA* and call your healthcare provider or get emergency medical help IMMEDIATELY if you:
 - Have trouble breathing
 - Have drowsiness with slowed breathing
 - Have slow, shallow breathing (little chest movement with breathing)
 - Feel faint, very dizzy, confused, or have unusual symptoms

These symptoms can be a sign that you have taken too much *FENTORA* or the dose is too high for you.

These symptoms may lead to serious problems or death if not treated right away.

2. **Decreased blood pressure.** This can make you feel dizzy or lightheaded when you stand up.
3. **Physical dependence. Do not stop taking *FENTORA* or taking any other opioid without talking to your healthcare provider.** You could become sick with uncomfortable withdrawal symptoms because your body has become used to these medicines. Physical dependency is not the same as drug addiction.
4. **A chance of abuse or addiction.** This chance is higher if you are or have been addicted to or abused other medicines, street drugs, or alcohol, or have a history of mental health problems.
5. **Pain, irritation, or sores at the application site (on your gum, on the inside of your cheek, or under your tongue).**

The most common side effects of *FENTORA* are:

- Nausea
- Vomiting
- Dizziness
- Low red blood cell count
- Tiredness
- Swelling of the arms, hands, legs and feet
- Headache

Constipation is a very common side effect of opioid pain medicines including *FENTORA* and is unlikely to go away without treatment. Talk to your healthcare provider about prevention or treatment of constipation while taking *FENTORA*.

Talk to your healthcare provider if you have any side effects.

These are not all the possible side effects of *FENTORA*. For more information, ask your healthcare provider or pharmacist or call 1-800-896-5855.

You are encouraged to report side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch, call 1-800-FDA-1088, or fax to 1-800-FDA-0178.

This information does not take the place of talking with your doctor for medical advice about your condition or treatment.

Please see the [Medication Guide](#) located at the end of the [Full Prescribing Information](#).

References: 1. Portenoy RK, Taylor D, Messina J, Tremmel L. A randomized, placebo-controlled study of fentanyl buccal tablet for breakthrough pain in opioid-treated patients with cancer. *Clin J Pain*. 2006;22(9):805-811. 2. Fentora [package insert]. Frazer, PA: Cephalon Inc.; 2013.