

9. Instruct patients NOT to share FENTORA and that sharing FENTORA with anyone else could result in the other individual's death due to overdose.
10. Make patients aware that FENTORA contains fentanyl which is a strong pain medication similar to hydromorphone, methadone, morphine, oxycodone, and oxymorphone.
11. Instruct patients that the active ingredient in FENTORA, fentanyl, is a drug that some people abuse. FENTORA should be taken only by the patient it was prescribed for, and it should be protected from theft or misuse in the work or home environment.
12. Instruct patients that FENTORA tablets are not to be swallowed whole; this will reduce the effectiveness of the medication. Tablets are to be placed between the cheek and gum above a molar tooth and allowed to dissolve. After 30 minutes if remnants of the tablet still remain, patients may swallow it with a glass of water.
13. Caution patients to talk to their doctor if breakthrough pain is not alleviated or worsens after taking FENTORA.
14. Instruct patients to use FENTORA exactly as prescribed by their doctor and not to take FENTORA more often than prescribed.
15. Caution patients that FENTORA can affect a person's ability to perform activities that require a high level of attention (such as driving or using heavy machinery). Warn patients taking FENTORA of these dangers and counsel them accordingly.
16. Warn patients to not combine FENTORA with alcohol, sleep aids, or tranquilizers except by the orders of the prescribing physician, because dangerous additive effects may occur, resulting in serious injury or death.
17. Inform female patients that if they become pregnant or plan to become pregnant during treatment with FENTORA, they should ask their doctor about the effects that FENTORA (or any medicine) may have on them and their unborn children.
18. Advise patients and caregivers that if they have been receiving treatment with FENTORA and the medicine is no longer needed they should flush any remaining product down the toilet, and if they then need further assistance, contact Cephalon, Inc., at 1-800-896-5855.

17.2 Disposal of Unopened FENTORA Blister Packages When No Longer Needed

Patients and members of their household must be advised to dispose of any unopened blister packages remaining from a prescription as soon as they are no longer needed.

To dispose of unused FENTORA, remove FENTORA tablets from blister packages and flush down the toilet. Do not flush the FENTORA blister packages or cartons down the toilet.

Detailed instructions for the proper storage, administration, disposal, and important instructions for managing an overdose of FENTORA are provided in the FENTORA *Medication Guide*. Instruct patients to read this information in its entirety and provide an opportunity to have their questions answered.

In the event that a caregiver requires additional assistance in disposing of excess unusable tablets that remain in the home after a patient has expired, instruct them to call the Cephalon toll-free number (1-800-896-5855) or seek assistance from their local DEA office.

MEDICATION GUIDE

FENTORA[®] (fen-tor-a) CII (fentanyl buccal tablet)

100 mcg, 200 mcg, 300 mcg, 400 mcg,
600 mcg, 800 mcg

IMPORTANT:

1. **Do not use FENTORA unless you are regularly using other opioid pain medicines around-the-clock for your constant cancer pain and your body is used to these medicines.**
2. **Keep FENTORA in a safe place away from children. Accidental use by a child is a medical emergency and can result in death. If a child accidentally takes FENTORA, get emergency help right away.**

Read the Medication Guide that comes with FENTORA before you start taking it and each time you get a new prescription. There may be new information. This Medication Guide does not take the place of talking to your doctor about your medical condition or your treatment. Share this important information with members of your household.

What is the most important information I should know about FENTORA?

1. **FENTORA can cause life-threatening breathing problems which can lead to death:**
 - if you are not regularly using other opioid pain medicines around-the-clock for your constant cancer pain and your body is not used to these medicines. This means that you are not opioid tolerant.
 - if you do not use it exactly as prescribed by your doctor.
2. **Your doctor will prescribe a starting dose of FENTORA that is different than other fentanyl containing medicines you may have been taking. Do not substitute FENTORA for other fentanyl medicines, including Actiq[®], without talking with your doctor.**

What is FENTORA?

- FENTORA is a prescription medicine that contains the medicine fentanyl. **FENTORA is a federally controlled substance (CII) because it is a strong opioid pain medicine that can be abused by people who abuse prescription medicines or street drugs.**
- **FENTORA is used to treat breakthrough pain in adult patients with cancer (18 years of age and older) who are regularly using other opioid pain medicines around-the-clock for their constant cancer pain.** FENTORA is started only after you have been taking other opioid pain medicines and your body has gotten used to them (you are opioid tolerant). **DO NOT USE FENTORA if you are not opioid tolerant.**

- You must stay under your doctor's care while taking FENTORA.
- **FENTORA must not be used for the treatment of short-term pain from injuries, surgery, and headaches, including migraines.**
- **FENTORA should be placed in the mouth, against your gum and allowed to dissolve.** You may feel a gentle bubbling sensation between your cheek and gum as the tablet dissolves. FENTORA is not meant to be chewed or swallowed.
- **Prevent theft and misuse. Keep FENTORA in a safe place** to protect it from being stolen since it can be a target for people who abuse narcotic medicines or street drugs.
- **Never give FENTORA to anyone else**, even if they have the same symptoms you have. It may harm them and even cause death.
- **Selling or giving away this medicine is against the law.**

Who should not take FENTORA?

Do Not Take FENTORA:

- if you are not regularly using other opioid pain medicines around-the-clock for your constant cancer pain.
- **for the treatment of short-term pain from injuries, surgery, and headaches, including migraines.**
- **if you are allergic to anything in FENTORA.** The active ingredient is fentanyl. See the end of this Medication Guide for a complete list of ingredients in FENTORA.

What should I tell my doctor before starting FENTORA?

Tell your doctor about all of your medical and mental problems, especially the ones listed below:

- Trouble breathing or lung problems such as asthma, wheezing, or shortness of breath
- A head injury or brain problem
- Liver or kidney problems
- Seizures (convulsions or fits)
- Slow heart rate or other heart problems
- Low blood pressure
- Mental problems including major depression or hallucinations (seeing or hearing things that are not there)
- A past or present drinking problem or alcoholism, or a family history of this problem
- A past or present drug abuse or addiction problem, or a family history of this problem

Tell your doctor if you are:

- **pregnant or planning to become pregnant.** FENTORA may harm your unborn baby.
- **breast feeding.** FENTORA passes through your breast milk, and it can cause serious harm to your baby. **You should not use FENTORA while breast feeding.**

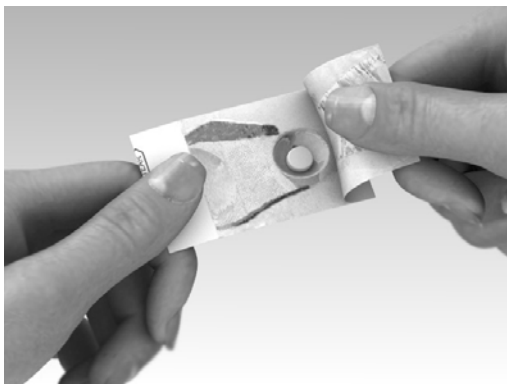
Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal and dietary supplements. Some medicines may cause serious or life-threatening medical problems when taken with FENTORA. Sometimes, the doses of certain medicines and FENTORA need to be changed if used together.

Do not take any medicine while using FENTORA until you have talked to your doctor. Your doctor will tell you if it is safe to take other medicines while you are using FENTORA. Be especially careful about taking other medicines that make you sleepy such as other pain medicines, anti-depressant medicines, sleeping pills, anxiety medicines, antihistamines, or tranquilizers.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist.

How should I use FENTORA?

- Use FENTORA exactly as prescribed by your doctor. Do not use FENTORA more often than prescribed.
 - Use **1 dose** of FENTORA for an episode of breakthrough cancer pain. When the amount of FENTORA is being adjusted by your doctor, a dose may include more than 1 tablet.
 - If your breakthrough cancer pain is not relieved after 30 minutes, use **ONLY 1** more dose of FENTORA at this time.
 - Wait at least 4 more hours before using FENTORA again for another episode of breakthrough cancer pain.
 - Remember you must continue taking your regularly used around-the-clock opioid medicine while taking FENTORA.
- Talk to your doctor if your dose of FENTORA does not relieve your breakthrough cancer pain. Your doctor will decide if your dose of FENTORA needs to be changed.
- Talk to your doctor if you have more than 4 episodes of breakthrough cancer pain per day. The dose of your around-the-clock opioid pain medicine may need to be adjusted.
- FENTORA comes packaged in a blister card. **Do not open the blister until ready to use.** Separate one of the blister units from the blister card by tearing apart at the perforations. Bend the blister unit along the line where indicated. Peel back foil on blister pack to expose tablet.



- **DO NOT push the tablet through the foil** on the blister pack because this could damage the tablet.
- **Once removed from the blister pack, FENTORA must be used right away.**
- **Place a FENTORA tablet in your mouth above a rear molar tooth between the upper cheek and gum and leave in place until the tablet is dissolved. This generally takes between 14 to 25 minutes. After 30 minutes if there is any tablet left, swallow it with a glass of water.** If you cannot take the medicine in this manner, tell your doctor who will advise you what to do. Do not split the tablet.



- **Do not bite, chew or suck FENTORA tablets.** If you do so, you will swallow more of the medicine and get less relief for your breakthrough cancer pain.
- Do not split the FENTORA tablet. The FENTORA tablet should be used whole.
- If you begin to feel dizzy, sick to your stomach, or very sleepy before the tablet is completely dissolved, rinse your mouth with water and spit the remaining pieces of the tablet into a sink or toilet right away. Rinse the sink or flush the toilet to dispose of any remaining tablet pieces.
- **If you take too much FENTORA or overdose, call 911 for emergency help.**

What should I avoid while taking FENTORA?

- **Do not drive, operate heavy machinery, or do other dangerous activities** until you know how FENTORA affects how alert you are. FENTORA can make you

sleepy. Ask your doctor when it is okay to do these activities.

- **Do not drink alcohol while using FENTORA.** It can increase your chance of getting dangerous side effects.
- **Do not take any medicine while using FENTORA until you have talked to your doctor. Your doctor will tell you if it is safe to take other medicines while you are using FENTORA. Be especially careful about taking other medicines that make you sleepy such as other pain medicines, anti-depressant medicines, sleeping pills, anxiety medicines, antihistamines, or tranquilizers.**

What are the possible or reasonably likely SIDE EFFECTS of FENTORA?

- **FENTORA can cause serious breathing problems that can become life-threatening, especially if used the wrong way. See “What is the most important information I should know about FENTORA?”**

Call your doctor or get emergency medical help right away if you:

- **have trouble breathing**
- **have extreme drowsiness with slowed breathing**
- **have slow, shallow breathing (little chest movement with breathing)**
- **feel faint, very dizzy, confused, or have unusual symptoms**

The above symptoms mean that you have taken too much (overdose) FENTORA or the dose is too high for you. **These symptoms may lead to serious problems or death if not treated right away. Do not take another dose of FENTORA.**

- **FENTORA can cause pain or sores at the application site (on your gum or the inside of your cheek).** Tell your doctor if this is a problem for you.
- **FENTORA can cause your blood pressure to drop.** This can make you feel dizzy if you get up too fast from sitting or lying down.
- **FENTORA can cause physical dependence.** Do not stop taking FENTORA or any other opioid without talking to your doctor. You could become sick with uncomfortable withdrawal symptoms because your body has become used to these medicines. Physical dependence is not the same as drug addiction.
- **There is a chance of abuse or addiction with FENTORA.** The chance is higher if you are or have been addicted to or abused other medications, street drugs, or alcohol, or if you have a history of mental problems.
- **The most common side effects of FENTORA** are nausea, vomiting, dizziness, sleepiness, headache, and constipation. Constipation (not often enough or hard bowel movements) is a very common side effect of pain medicines (opioids) including FENTORA and is unlikely to go away without treatment. Talk to your doctor about dietary changes, and the use of laxatives

(medicines to treat constipation) and stool softeners to prevent or treat constipation while taking FENTORA.

Talk to your doctor about any side effects that bother you or that do not go away.

These are not all the possible side effects of FENTORA. For a complete list, ask your doctor.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store FENTORA?

- **Keep FENTORA in a safe and secure place away from children and from anyone for whom it has not been prescribed. Accidental use by a child is a medical emergency and can result in death. If a child accidentally takes FENTORA, get emergency help right away.**
- **FENTORA is supplied in single sealed child-resistant blister packages.**
- Do NOT remove FENTORA from its blister packaging for storage in a temporary container, such as a pill box.
- Store FENTORA at room temperature, 59° to 86°F (15° to 30°C) until ready to use.
- **Always keep FENTORA in a secure place to protect from theft.**

How should I dispose of unopened FENTORA tablets when they are no longer needed?

- Dispose of any unopened FENTORA tablets remaining from a prescription as soon as they are no longer needed.
- **To dispose of unused FENTORA, remove FENTORA tablets from blister packages and flush down the toilet. Do not flush the FENTORA blister packages or cartons down the toilet.**
- If you need help with disposal of FENTORA, call Cephalon, Inc., at 1-800-896-5855.

General Information About the Safe and Effective Use of FENTORA

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Use FENTORA only for the purpose for which it was prescribed. Do not give FENTORA to other people, even if they have the same symptoms you have. **FENTORA can harm other people and even cause death. Sharing FENTORA is against the law.**

This Medication Guide summarizes the most important information about FENTORA. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about FENTORA that is written for healthcare professionals. You can also call Cephalon, Inc., at 1-800-896-5855.

What are the ingredients of FENTORA?

Active Ingredient: fentanyl citrate

Inactive Ingredients: mannitol, sodium starch glycolate, sodium bicarbonate, sodium carbonate, citric acid, and magnesium stearate.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Rx Only

Cephalon, Inc.
Frazer, PA 19355

FENTORA is a registered trademark of CIMA LABS, INC., a wholly owned subsidiary of Cephalon, Inc.

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