

Medication Guide

FENTORA™ (fen-tor-a)
(fentanyl buccal tablet)

CII

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

IMPORTANT: 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*?

- FENTORA* can cause life-threatening breathing problems which can lead to death:**
 - if it is used by anyone who is not already taking other opioid pain medicines and their body is not used to these medicines (not opioid tolerant)
 - if it is not used exactly as prescribed
- 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 already taking other opioid pain medicines for their constant (around-the-clock) 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 short-term pain from injuries and surgery.
- 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 already taking other opioid pain medicines for your constant (around-the-clock) cancer pain. **Never use *FENTORA* for short-term pain from injuries and surgery.**
- **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 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.** Do not take *FENTORA* more often than prescribed. **Talk to your doctor about your pain. Your doctor can decide if your dose of *FENTORA* needs to be changed.**
- *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.
- 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 have more than 4 episodes of breakthrough cancer pain per day, talk to your doctor. The dose of around-the-clock pain medicine may need to be adjusted.
- 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

These can be symptoms 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.**

- ***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.

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.
- 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, USA**

Reference Number 074000106.XX
March 2007

U.S. Patent Nos. 6,200,604 and 6,974,590