

MEDICATION GUIDE

Oral Transmucosal Fentanyl Citrate (OTFC) CII

(fentanyl citrate) oral transmucosal lozenge

200 mcg, 400 mcg, 600 mcg, 800 mcg, 1200 mcg, 1600 mcg

IMPORTANT:

Do not use Oral Transmucosal Fentanyl Citrate (OTFC) unless you are regularly using another opioid pain medicine around-the-clock for at least one week or longer for your cancer pain and your body is used to these medicines (this means that you are opioid tolerant). You can ask your healthcare provider if you are opioid tolerant.

Keep OTFC in a safe place away from children.

Get emergency medical help right away if:

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

These are medical emergencies that can cause death. If possible, remove OTFC from the mouth.

Read this Medication Guide completely before you start using OTFC 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 healthcare provider about your medical condition or your treatment. Share this important information with members of your household and other caregivers.

What is the most important information I should know about Oral Transmucosal Fentanyl Citrate (OTFC)?

OTFC can cause life-threatening breathing problems which can lead to death:

1. **Do not use OTFC if you are not opioid tolerant.**
2. If you stop taking your around-the-clock opioid pain medicine for your cancer pain, **you must stop** using OTFC. You may no longer be opioid tolerant. Talk to your healthcare provider about how to treat your pain.
3. **Use OTFC exactly as prescribed by your healthcare provider.**
 - You must not use more than 1 unit of OTFC at a time and no more than 2 units of OTFC during each episode of breakthrough cancer pain.
 - You must wait at least 4 hours before treating a new episode of breakthrough pain. **See the Medication Guide section “How should I use Oral Transmucosal Fentanyl Citrate (OTFC)?” and the Patient Instructions for Use at the end of this Medication Guide about how to use OTFC the right way.**
4. **Do not switch from OTFC to other medicines that contain fentanyl without talking with your healthcare provider.** The amount of fentanyl in a dose of OTFC is not the same as the amount of fentanyl in other medicines that contain fentanyl. Your healthcare provider will prescribe a starting dose of OTFC that may be different than other fentanyl containing medicines you may have been taking.
5. **Do not** use OTFC for short-term pain that you would expect to go away in a few days, such as:
 - pain after surgery
 - headache or migraine
 - dental pain

6. **Never give OTFC to anyone else**, even if they have the same symptoms you have. It may harm them or even cause death.

OTFC is a federally controlled substance (CII) because it is a strong opioid (narcotic) pain medicine that can be misused by people who abuse prescription medicines or street drugs.

- **Prevent theft, misuse or abuse. Keep OTFC in a safe place** to protect it from being stolen. OTFC can be a target for people who abuse opioid (narcotic) medicines or street drugs.
 - **Selling or giving away this medicine is against the law.**
7. OTFC is available only through a program called the **Transmucosal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS) Access** program. To receive OTFC, you must:
 - talk to your healthcare provider
 - understand the benefits and risks of OTFC
 - agree to all of the instructions
 - sign the Patient-Prescriber Agreement form

What is Oral Transmucosal Fentanyl Citrate (OTFC)?

- OTFC is a prescription medicine that contains the medicine fentanyl.
- OTFC is used to manage breakthrough pain in adults (16 years of age and older) with cancer who are already routinely taking other opioid pain medicines around-the-clock for cancer pain.
- OTFC is started only after you have been taking other opioid pain medicines and your body has become used to them (you are opioid tolerant). Do not use OTFC if you are not opioid tolerant.
- OTFC is a lozenge (attached to a handle) that you place between your cheek and lower gum and suck on to dissolve.
- You must stay under your healthcare provider's care while using OTFC .
- OTFC is only:
 - o available through the TIRF REMS Access program
 - o given to people who are opioid tolerant

It is not known if OTFC is safe and effective in children under 16 years of age.

Who should not use Oral Transmucosal Fentanyl Citrate (OTFC)?

Do not use OTFC:

- **if you are not opioid tolerant. Opioid tolerant means that you are already taking other opioid pain medicines around-the-clock for at least one week or longer 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:
 - o pain after surgery
 - o headache or migraine
 - o dental pain
- if you are allergic to any of the ingredients in OTFC . See the end of this Medication Guide for a complete list of ingredients in OTFC.

What should I tell my healthcare provider before using Oral Transmucosal Fentanyl Citrate (OTFC)?

Before using OTFC, tell your healthcare provider if you:

- have trouble breathing or lung problems such as asthma, wheezing, or shortness of breath
- have or had a head injury or brain problem
- have liver or kidney problems
- have seizures
- have a slow heart rate or other heart problems
- have low blood pressure
- have mental problems including major depression, schizophrenia or hallucinations (seeing or hearing things that are not there)
- have a past or present drinking problem (alcoholism), or a family history of drinking problems
- have a past or present drug abuse or addiction problem, or a family history of a drug abuse problem or addiction problem
- have diabetes. Each OTFC unit contains about ½ teaspoon (2 grams) of sugar.
- have any other medical conditions
- are pregnant or plan to become pregnant. OTFC may cause serious harm to your unborn baby.
- are breastfeeding or plan to breastfeed. OTFC passes into your breast milk. It can cause serious harm to your baby. You should not use OTFC while breastfeeding.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Some medicines may cause serious or life-threatening side effects when taken with OTFC. Sometimes, the doses of certain medicines and OTFC may need to be changed if used together.

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

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I use Oral Transmucosal Fentanyl Citrate (OTFC)?

Before you can begin to use OTFC:

- Your healthcare provider will explain the TIRF REMS Access program to you.
- You will sign the TIRF REMS Access program Patient-Prescriber Agreement form.
- OTFC is only available at pharmacies that are part of the TIRF REMS Access program. Your healthcare provider will let you know the pharmacy closest to your home where you can have your OTFC prescription filled.

Using OTFC:

- **Use OTFC exactly as prescribed. Do not use OTFC more often than prescribed.**
- Your healthcare provider will change the dose until you and your healthcare provider find the right dose for you.
- **See the detailed Patient Instructions for Use at the end of this Medication Guide for information about how to use OTFC the right way.**
- Finish the OTFC unit completely in 15 minutes to get the most relief. If you finish OTFC too quickly, you will swallow more of the medicine and get less relief.
- **Do not bite or chew OTFC. You will get less relief for your breakthrough cancer pain.**

- You may drink some water before using OTFC but you should not drink or eat anything while using OTFC.
- You must not use more than 2 units of OTFC during each episode of breakthrough cancer pain:
 - Use **1** unit for an episode of breakthrough cancer pain. Finish the unit over 15 minutes.
 - If your breakthrough cancer pain is not relieved 15 minutes after you finished the OTFC unit, use **only 1** more unit of OTFC at this time.
 - If your breakthrough pain does not get better after the second unit of OTFC, call your healthcare provider for instructions. **Do not use another unit of OTFC at this time.**
- Wait at least **4** hours before treating a new episode of breakthrough cancer pain with OTFC.
- It is important for you to keep taking your around-the-clock opioid pain medicine while using OTFC.
- Talk to your healthcare provider if your dose of OTFC does not relieve your breakthrough cancer pain. Your healthcare provider will decide if your dose of OTFC needs to be changed.
- Talk to your healthcare provider 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.
- If you begin to feel dizzy, sick to your stomach, or very sleepy before OTFC is completely dissolved, remove OTFC from your mouth.
- If you use too much OTFC or overdose, you or your caregiver should call for emergency medical help or have someone take you to the nearest hospital emergency room right away.

What should I avoid while using Oral Transmucosal Fentanyl Citrate (OTFC)?

- **Do not drive, operate heavy machinery, or do other dangerous activities** until you know how OTFC affects you. OTFC can make you sleepy. Ask your healthcare provider when it is okay to do these activities.
- **Do not drink alcohol while using OTFC.** It can increase your chance of getting dangerous side effects.

What are the possible side effects of Oral Transmucosal Fentanyl Citrate (OTFC)?

OTFC can cause serious side effects, including:

1. **Breathing problems that can become life-threatening.** See “**What is the most important information I should know about Oral Transmucosal Fentanyl Citrate (OTFC)?**”
Call your healthcare provider or get emergency medical help right away 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 other unusual symptoms
 These symptoms can be a sign that you have used too much OTFC or the dose is too high for you. **These symptoms may lead to serious problems or death if not treated right away. If you have any of these symptoms, do not use any more OTFC until you have talked to your healthcare provider.**
2. **Decreased blood pressure.** This can make you feel dizzy or lightheaded if you get up too fast from sitting or lying down.
3. **Physical dependence. Do not stop taking OTFC or 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 ever been addicted to or abused other medicines, street drugs, or alcohol, or if you have a history of mental health problems.

The most common side effects of OTFCare:

- nausea
- vomiting
- dizziness
- sleepiness
- weakness
- headache
- anxiety
- confusion
- depression
- rash
- trouble sleeping

Constipation (not often enough or hard bowel movements) is a very common side effect of pain medicines (opioids) including OTFC and is unlikely to go away without treatment. Talk to your healthcare provider about dietary changes, and the use of laxatives (medicines to treat constipation) and stool softeners to prevent or treat constipation while taking OTFC.

OTFC contains sugar. Cavities and tooth decay can happen in people taking OTFC. When taking OTFC, you should talk to your dentist about proper care of your teeth.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of OTFC. For more information, ask your healthcare provider or pharmacist.

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 Oral Transmucosal Fentanyl Citrate (OTFC)?

- **Always keep OTFC in a safe place away from children and from anyone for whom it has not been prescribed.** Protect OTFC from theft.
- You can use the OTFC Child Safety Kit to help you store OTFC and your other medicines out of the reach of children. It is very important that you use the items in the OTFC Child Safety Kit to help protect the children in your home or visiting your home.
- If you were not offered a Child Safety Kit when you received your medicine, call Cephalon, Inc., at 1-800-896-5855 to request one.

The OTFC Child Safety Kit contains important information on the safe storage and handling of OTFC.

The Child Safety Kit includes:

- **A child-resistant lock that** you use to secure the storage space where you keep OTFC (See Figure 1).





Figure 1

- A **portable locking pouch** for you to keep a small supply of OTFC nearby. The rest of your OTFC must be kept in a locked storage space.
- Keep this pouch secured with its lock and keep it out of the reach and sight of children (See Figure 2).



Figure 2

- A **child-resistant temporary storage bottle** (See Figure 3).



Figure 3

- Store OTFC at room temperature, 59°F to 86°F (15°C to 30°C) until ready to use.
- Do not freeze OTFC.
- **Keep OTFC in the original sealed child-resistant blister package. Do not open the blister package until you are ready to use OTFC.**
- Keep OTFC dry.

How should I dispose of Oral Transmucosal Fentanyl Citrate (OTFC) units when they are no longer needed?

Disposing of OTFC units after use:

Partially used OTFC units may contain enough medicine to be harmful or fatal to a child or other adults who have not been prescribed OTFC. **You must properly dispose of the OTFC handle right away after use even if there is little or no medicine left on it.**

After you have finished the OTFC unit and the medicine is totally gone, throw the handle away in a place that is out of the reach of children.

If **any** medicine remains on the used OTFC unit after you have finished:

- Place the used OTFC unit under hot running water until the medicine is gone, and then throw the handle away out of the reach of children and pets (See Figure 4).



Figure 4

Temporary Storage of Used OTFC Units:

- If you did not finish the entire OTFC unit and you cannot dissolve the medicine under hot running water right away, put the used OTFC unit in the temporary storage bottle that you received in the OTFC Child Safety Kit. Push the used OTFC unit into the opening on the top until it falls completely into the bottle. **Never leave unused or partially used OTFC units where children or pets can get to them** (See Figure 5).



Figure 5

Disposing of Used OTFC Units from the Temporary Storage Bottle:

You must dispose of all used OTFC units in the temporary storage bottle **at least one time each day**, as follows:

1. To open the temporary storage bottle, push down on the cap until you are able to twist the cap to the left to remove it (See Figure 6).



Figure 6

2. Remove one OTFC unit from the temporary storage bottle. Hold the OTFC by its handle over the toilet bowl.
3. Using wire-cutting pliers, cut the medicine end off so that it falls into the toilet.
4. Throw the handle away in a place that is out of the reach of children.
5. Repeat these 3 steps for each OTFC handle that is in the storage bottle. There should not be more than 4 handles in the temporary storage bottle for 1 day.
6. Flush the toilet twice.

Do not flush entire unused OTFC units, OTFC handles, or blister packages down the toilet.

Disposing of unopened OTFC units: Dispose of any unopened OTFC units remaining from a prescription as soon as they are no longer needed, as follows:

1. Remove all OTFC from the locked storage space (See Figure 7).

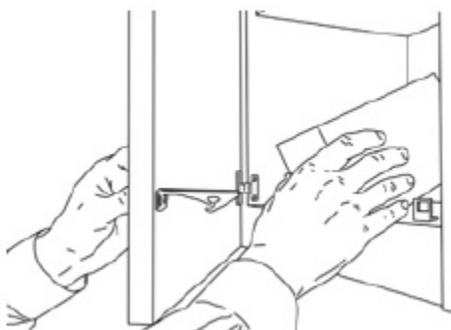


Figure 7

- 2.

Remove one OTFC unit from its blister package by using scissors to cut off the marked end and then peel back the blister backing (See Figures 8A and 8B).



Figure 8A Figure 8B

3. Hold OTFC by its handle over the toilet bowl. Use wire-cutting pliers to cut the medicine end off so that it falls into the toilet (See Figures 9A and 9B).



Figure 9A Figure 9B

4. Throw the handle away in a place that is out of the reach of children (See Figure 10).



Figure 10

5. Repeat steps 1 through 4 for each OTFC unit.
6. Flush the toilet twice after the medicine ends from 5 OTFC units have been cut off (See Figure 11). Do not flush more than 5 OTFC units at a time.





Figure 11

- Do not flush entire unused OTFC units, OTFC handles, or blister packages down the toilet.

If you need help with disposal of OTFC, call Cephalon, Inc., at 1-800-896-5855, or call your local Drug Enforcement Agency (DEA) office.

General information about Oral Transmucosal Fentanyl Citrate (OTFC)

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

This Medication Guide summarizes the most important information about OTFC. If you would like more information, talk with your healthcare provider or pharmacist. You can ask your pharmacist or healthcare provider for information about OTFC that is written for healthcare professionals.

For more information about the TIRF REMS Access program, go to www.TIRFREMSAccess.com or call 1-866-822-1483.

What are the ingredients of Oral Transmucosal Fentanyl Citrate (OTFC)?

Active Ingredient: fentanyl citrate

Inactive Ingredients: sugar, citric acid, dibasic sodium phosphate, artificial berry flavor, magnesium stearate, modified food starch and confectioner's sugar.

Patient Instructions for Use

Before you use OTFC, it is important that you read the Medication Guide and these Patient Instructions for Use. Be sure that you read, understand, and follow these Patient Instructions for Use so that you use OTFC the right way. Ask your healthcare provider or pharmacist if you have any questions about the right way to use OTFC.

When you get an episode of breakthrough cancer pain, use the dose of OTFC prescribed by your healthcare provider as follows:

- You may drink some water before using OTFC but you should not drink or eat anything while using OTFC.
- Each unit of OTFC is sealed in its own blister package (See Figure 12). **Do not open the blister package until you are ready to use OTFC.**



Figure 12

- When you are ready to use OTFC, cut open the package using scissors. Peel back the blister backing, and remove the OTFC unit (See Figures 13A and 13B). The end of the unit printed with “FENTANYL” and the strength number of the unit (“200”, “400”, “600”, “800”, “1200”, or “1600”) is the medicine end that is to be placed in your mouth. Hold the OTFC unit by the handle (See Figure 14).

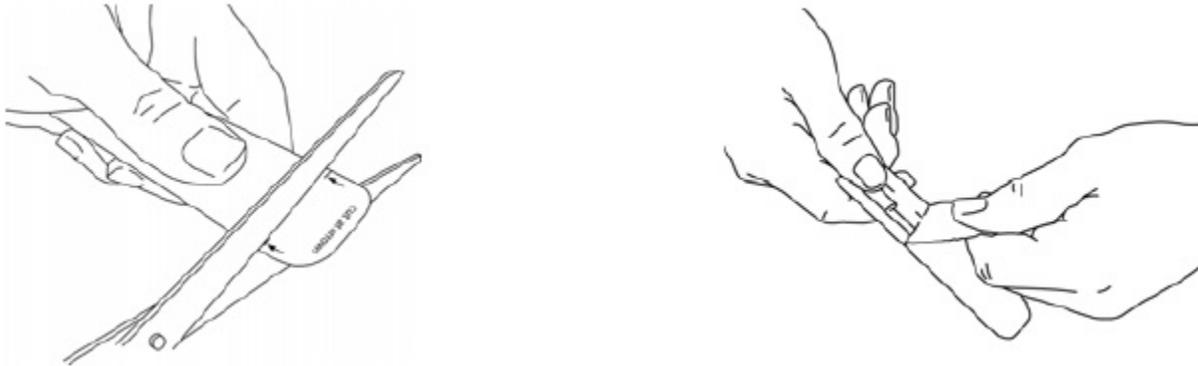


Figure 13A Figure 13B

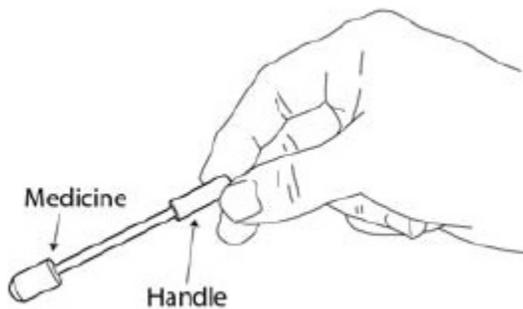


Figure 14

1. Place the medicine end of the OTFC unit in your mouth between your cheeks and gums and actively suck on the medicine.
2. Move the medicine end of the OTFC unit around in your mouth, especially along the inside of your cheeks (See Figure 15).

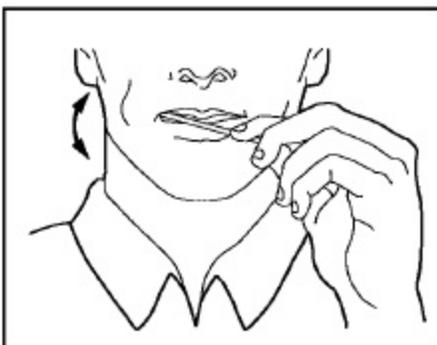


Figure 15

3. Twirl the handle often.
4. Finish the OTFC unit completely over 15 minutes to get the most relief. If you finish OTFC too quickly, you will swallow more of the medicine and get less relief.
5. **Do not bite or chew OTFC. You will get less relief for your breakthrough cancer pain.**
 - If you cannot finish all of the medicine on the OTFC unit and cannot dissolve the medicine under hot tap water right away, immediately put the OTFC unit in the temporary storage bottle for safe keeping (See Figure 16).
 - Push the OTFC unit into the opening on the top until it falls completely into the bottle. You must properly dispose of the OTFC unit as soon as you can.



Figure 16

See “**How should I dispose of OTFC units when they are no longer needed?**” for proper disposal of OTFC.

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

Distributed by:

TEVA PHARMACEUTICALS USA, Inc.
North Wales, PA 19454

Revised January 2015

OTF-012

OTFMG-012

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Printed in USA