

Medication Guide

Oral Transmucosal Fentanyl Citrate (OTFC) 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1200 mcg, 1600 mcg



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12001058
Rx only



WARNING: You MUST keep oral transmucosal fentanyl citrate in a safe place out of the reach of children. Accidental ingestion by a child is a medical emergency and can result in death. **If a child accidentally takes oral transmucosal fentanyl citrate, get emergency help right away.**

Read the Medication Guide that comes with Oral Transmucosal Fentanyl Citrate 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 Oral Transmucosal Fentanyl Citrate (OTFC)?

- 1. OTFC 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.
- 2. Your doctor will prescribe a starting dose of OTFC that is different than other fentanyl containing medicines you may have been taking. Do not substitute OTFC for other fentanyl medicines without talking with your doctor.**

What is Oral Transmucosal Fentanyl Citrate (OTFC)?

- OTFC is a prescription medicine that contains the medicine fentanyl. **OTFC 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.**

OTFC is to be used only to treat breakthrough pain in adult patients with cancer (16 years of age and older) who are already taking other opioid pain medicines for their constant (around-the-clock) cancer pain. OTFC 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 OTFC if you are not opioid tolerant.**

- You must stay under your doctor's care while taking OTFC.
- **OTFC must not be used for short-term pain from injuries and surgery.**

- **Prevent theft and misuse. Keep OTFC 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 OTFC 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 Oral Transmucosal Fentanyl Citrate (OTFC)?

Do Not Take OTFC if you:

- are not already taking other opioid pain medicines for your constant (around-the-clock) cancer pain. **Never use OTFC for short-term pain from injuries or surgery** or pain that will go away in a few days, such as pain from doctor or dentist visits, or any short-lasting pain.
- **are allergic to anything in OTFC.** The active ingredient in OTFC is fentanyl. See the end of this Medication Guide for a complete list of ingredients in OTFC.

What should I tell my doctor before I start taking Oral Transmucosal Fentanyl Citrate (OTFC)?

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
- If you are diabetic. Each OTFC unit contains about ½ teaspoon (2 grams) of sugar.

Tell your doctor if you are:

- **pregnant or planning to become pregnant.** OTFC may harm your unborn baby.
- **breast-feeding.** Fentanyl passes through your breast milk and it can cause serious harm to your baby. **You should not use OTFC 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 OTFC. Sometimes, the doses of certain medicines and OTFC need to be changed if used together. **Do not take any medicine while using OTFC until you have talked to your doctor. Your doctor will tell you if it is safe to take other medicines while you are using OTFC. Be especially careful about 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 Oral Transmucosal Fentanyl Citrate (OTFC)?

- Use OTFC exactly as prescribed. Do not take OTFC more often than prescribed. **Talk to your doctor about your pain. Your doctor can decide if your dose of OTFC needs to be changed.**
- Each unit of OTFC is sealed in its own blister package.

- **Do not open the blister package until you are ready to use OTFC.**
- When you are ready to use OTFC, cut open the package using scissors and remove the OTFC unit.



- Place OTFC in your mouth between your cheeks and gums and actively suck on the medicine.
- Move OTFC around in your mouth, especially along your cheeks.
- Twirl the handle often.



- 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 pain.**
- You may drink some water before using OTFC but you should not drink or eat anything while using OTFC.
- If you begin to feel dizzy, sick to your stomach, or very sleepy before OTFC is completely dissolved, remove OTFC from your mouth. Dispose of OTFC right away or put it in the temporary storage bottle in the Child Safety Kit for later disposal.

If you have more than 4 episodes of breakthrough cancer pain per day, talk to your doctor. The dose of OTFC may need to be adjusted.

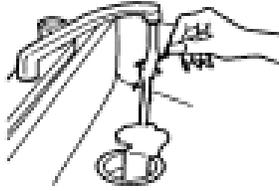
- **If you take too much OTFC or overdose, call 911 or your local emergency number for help.**

How should I dispose of Oral Transmucosal Fentanyl Citrate (OTFC) 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.** Please follow these directions to dispose of the handle:

1. Once 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.

2. If any medicine remains on the handle after you have finished, place the handle under hot running water until the medicine is gone, and then throw the handle away out of the reach of children and pets.



3. If you did not finish the entire OTFC unit and you cannot dissolve the medicine under hot running water right away, put the OTFC in the temporary storage bottle that you received in the OTFC Child Safety Kit for safe keeping. Open the child-resistant cap, and place the OTFC unit completely into the bottle and close the cap tightly. **Never leave unused or partially used OTFC units where children or pets can get to them.**
4. Dispose of the handles in the temporary storage bottle as soon as you can by following the directions in steps 1 and 2. You must dispose of all handles in the temporary storage bottle at least once a day.

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

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

- **Do not drive, operate heavy machinery, or do other dangerous activities** until you know how OTFC affects how alert you are. OTFC can make you sleepy. Ask your doctor 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.
- **Do not take any medicine while using OTFC until you have talked to your doctor.** Your doctor will tell you if it is safe to take other medicines while you are using OTFC. Be especially careful about 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 Oral Transmucosal Fentanyl Citrate (OTFC)?

- **OTFC 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 OTFC?”
- **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) OTFC or the dose is too high for you. **These symptoms may lead to serious problems or death if not treated right away.**

- **OTFC can cause your blood pressure to drop.** This can make you feel dizzy if you get up too fast from sitting or lying down.
- **OTFC can cause physical dependence.** Do not stop taking OTFC 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 dependency is not the same as drug addiction.
- **There is a chance of abuse or addiction with OTFC.** 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 OTFC are nausea, vomiting, dizziness and sleepiness. Other side effects include headache, low energy and constipation. 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 doctor 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 have occurred in patients taking OTFC. When taking OTFC, you should talk to your dentist about proper care of your teeth.

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 OTFC. For a complete list, ask your doctor.

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

- **Keep OTFC 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 OTFC, get emergency help right away.**
- **OTFC is supplied in single sealed child-resistant blister packages.** Store OTFC at room temperature, 68° to 77°F (20° to 25°C) until ready to use.
- **Always keep OTFC in a secure place to protect from theft.**

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

- Dispose of any unopened OTFC units remaining from a prescription as soon as they are no longer needed.
- If you are no longer using OTFC or if you have unused OTFC in your home, please follow these steps to dispose of the OTFC as soon as possible.
 1. Remove all OTFC from the locked storage space.
 2. Remove one OTFC unit from its blister package using scissors, and 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 steps 2, 3, and 4 for each OTFC.
 6. Flush the toilet twice after 5 OTFC units have been cut. Do not flush more than 5 OTFC units at a time.
- Do not flush entire unused OTFC units, OTFC handles, or blister packages down the toilet.

If you need help with disposal of OTFC, call 1-800-391-5962.

General Information About the Safe and Effective Use of 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 doctor. You can also ask your pharmacist or doctor for information about OTFC that is written for healthcare professionals. You can also call 1-800-391-5962.

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

Active Ingredient: fentanyl citrate

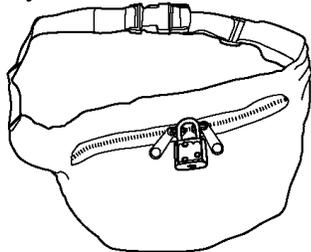
Inactive Ingredients: artificial raspberry flavor, citric acid, confectioner's sugar, dextrans, dibasic sodium phosphate, magnesium stearate and pregelatinized starch.

How do I use the Oral Transmucosal Fentanyl Citrate (OTFC) Child Safety Kit?

- 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 protect the children in your home.
- If you were not offered a Child Safety Kit when you received your medicine, call 1-800-391-5974 to request one.

The OTFC Child Safety Kit contains:

- **A child-resistant lock** for you to secure the storage space where you keep OTFC and any other medicines at home.



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



- A **child-resistant temporary storage bottle.**
- If for some reason you cannot finish the entire OTFC unit and cannot immediately dissolve the medicine under hot tap water, immediately put the OTFC unit in the temporary storage bottle for safe keeping.
 - Open the child-resistant cap, and place the OTFC unit completely into the bottle and close the cap tightly. You must properly dispose of the OTFC unit as soon as you can.
- See “How should I dispose of unopened OTFC units when they are no longer needed?” for proper disposal of OTFC.

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

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

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MG-0001, 0002, 0003, 0004, 0005, 0006