

Oral Transmucosal Fentanyl Citrate (or' əl • tranz mu-kō' s'l • fēn' tə-nīl • sīt' rāt)
oral transmucosal lozenge, CII

IMPORTANT:

Do not use oral transmucosal fentanyl citrate 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 oral transmucosal fentanyl citrate in a safe place away from children.

Get emergency medical help right away if:

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

These are medical emergencies that can cause death. If possible, remove oral transmucosal fentanyl citrate from the mouth.

Oral transmucosal fentanyl citrate is:

- A strong prescription pain medicine that contains an opioid (narcotic) that 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. Oral transmucosal fentanyl citrate 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 oral transmucosal fentanyl citrate if you are not opioid tolerant.
- An opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death.

Important information about oral transmucosal fentanyl citrate:

- **Get emergency help right away if you take too much oral transmucosal fentanyl citrate (overdose).** When you first start taking oral transmucosal fentanyl citrate, when your dose is changed, or if you take too much (overdose), serious or life-threatening breathing problems that can lead to death may occur.
- Taking oral transmucosal fentanyl citrate with other medicines that may make you sleepy, such as other pain medicines, anti-depressants, sleeping pills, anti-anxiety medicines, antihistamines, or tranquilizers, or with alcohol or street drugs can cause severe drowsiness, confusion, breathing problems, coma, and death.
- Never give anyone else your oral transmucosal fentanyl citrate. They could die from taking it. Store oral transmucosal fentanyl citrate away from children and in a safe place to prevent stealing or abuse. Selling or giving away oral transmucosal fentanyl citrate is against the law.
- If you stop taking your around-the-clock opioid pain medicine for your cancer pain, **you must stop** using oral transmucosal fentanyl citrate. You may no longer be opioid tolerant. Talk to your healthcare provider about how to treat your pain.
- Oral transmucosal fentanyl citrate is available only through a program called the **Transmucosal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS) Access** program. To receive oral transmucosal fentanyl citrate, you must:
 - talk to your healthcare provider
 - understand the benefits and risks of oral transmucosal fentanyl citrate
 - agree to all of the instructions
 - sign the Patient-Prescriber Agreement form
- Oral transmucosal fentanyl citrate 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 oral transmucosal fentanyl citrate prescription filled.
- Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

Do not take oral transmucosal fentanyl citrate 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.
- You have severe asthma, trouble breathing, or other lung problems.
- You have a bowel blockage or have narrowing of the stomach or intestines.
- You are allergic to any of the ingredients in oral transmucosal fentanyl citrate. See the end of this Medication Guide for a complete list of ingredients in oral transmucosal fentanyl citrate.
- You have short-term pain that you would expect to go away in a few days, such as:
 - pain after surgery
 - headache or migraine
 - dental pain

Before taking oral transmucosal fentanyl citrate, tell your healthcare provider if you have a history of:

- troubled breathing or lung problems such as asthma, wheezing, or shortness of breath
- head injury, seizures
- slow heart rate or other heart problems
- low blood pressure
- abuse of street or prescription drugs, alcohol addiction, or mental health problems
- diabetes. Each oral transmucosal fentanyl citrate unit contains about ½ teaspoon (2 grams) of sugar.
- mental problems [including major depression, schizophrenia or hallucinations (seeing or hearing things that are not there)]
- problems urinating
- liver, kidney, thyroid problems
- pancreas or gallbladder problems

Tell your healthcare provider if you are:

- **pregnant or planning to become pregnant.** Prolonged use of oral transmucosal fentanyl citrate during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
- **breastfeeding.** Oral transmucosal fentanyl citrate passes into breast milk and may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking oral transmucosal fentanyl citrate with certain other medicines can cause serious side effects that could lead to death.

When taking oral transmucosal fentanyl citrate:

- Do not change your dose. Take oral transmucosal fentanyl citrate exactly as prescribed by your healthcare provider.
- 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 oral transmucosal fentanyl citrate.**
- Finish the unit completely in 15 minutes to get the most relief. If you finish oral transmucosal fentanyl citrate too quickly, you will swallow more of the medicine and get less relief.
- **Do not bite or chew. You will get less relief for your breakthrough cancer pain.**
- You may drink some water before using oral transmucosal fentanyl citrate but you should not drink or eat anything while using oral transmucosal fentanyl citrate.
- You must not use more than 2 units of oral transmucosal fentanyl citrate 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 oral transmucosal fentanyl citrate unit, use **only 1** more unit of oral transmucosal fentanyl citrate at this time.
 - If your breakthrough pain does not get better after the second unit of oral transmucosal fentanyl citrate, call your healthcare provider for instructions. **Do not use another unit of oral transmucosal fentanyl citrate at this time.**
- Wait at least **4** hours before treating a new episode of breakthrough cancer pain with oral transmucosal fentanyl citrate.
- It is important for you to keep taking your around-the-clock opioid pain medicine.
- Talk to your healthcare provider if your dose of oral transmucosal fentanyl citrate does not relieve your breakthrough cancer pain. Your healthcare provider will decide if your dose of oral transmucosal fentanyl citrate 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 oral transmucosal fentanyl citrate is completely dissolved, remove oral transmucosal fentanyl citrate from your mouth.
- Do not stop taking oral transmucosal fentanyl citrate 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.
- After you stop taking, or when oral transmucosal fentanyl citrate is no longer needed, see **“How should I dispose of oral transmucosal fentanyl citrate units when they are no longer needed?”** for proper disposal of oral transmucosal fentanyl citrate.
- **DO NOT** Drive or operate heavy machinery, until you know how oral transmucosal fentanyl citrate affects you. Oral transmucosal fentanyl citrate can make you sleepy, dizzy, or lightheaded.
- **DO NOT** Drink alcohol or use prescription or over-the-counter medicines that contain alcohol. Using products containing alcohol during treatment with oral transmucosal fentanyl citrate may cause you to overdose and die.
- **DO NOT Switch from oral transmucosal fentanyl citrate to other medicines that contain fentanyl without talking to your healthcare provider.** The amount of fentanyl in a dose of oral transmucosal fentanyl citrate is not the same as the amount of fentanyl in other medicines that contain fentanyl. Your healthcare provider will prescribe a starting dose of oral transmucosal fentanyl citrate that may be different than other fentanyl containing medicines you may have been taking.

The possible side effects of oral transmucosal fentanyl citrate:

- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain, weakness, anxiety, depression, rash, trouble sleeping.
Call your healthcare provider if you have any of these symptoms and they are severe.
- Decreased blood pressure. This can make you feel dizzy or lightheaded if you get up too fast from sitting or lying down.
- Oral transmucosal fentanyl citrate contains sugar. Cavities and tooth decay can happen in people taking oral transmucosal fentanyl citrate. When taking oral transmucosal fentanyl citrate, you should talk to your dentist about proper care of your teeth.

Get emergency medical help if you have:

- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue, or throat, extreme drowsiness, light-headedness when changing positions, feeling faint, agitation, high body temperature, trouble walking, stiff muscles, or mental changes such as confusion.
- These symptoms can be a sign that you have used too much oral transmucosal fentanyl citrate 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 oral transmucosal fentanyl citrate until you have talked to your healthcare provider.**

These are not all the possible side effects of oral transmucosal fentanyl citrate. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. For more information go to dailymed.nlm.nih.gov

How should I store oral transmucosal fentanyl citrate?

- **Always keep oral transmucosal fentanyl citrate in a safe place away from children and from anyone for whom it has not been prescribed.** Protect oral transmucosal fentanyl citrate from theft.
 - You can use the oral transmucosal fentanyl citrate Child Safety Kit to help you store oral transmucosal fentanyl citrate and your other medicines out of the reach of children. It is very important that you use the items in the oral transmucosal fentanyl citrate 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 Mallinckrodt Pharmaceutical Child Safety Kit Request Line at 1-800-223-1499 to request one.

The oral transmucosal fentanyl citrate Child Safety Kit contains important information on the safe storage and handling of oral transmucosal fentanyl citrate.

The Child Safety Kit includes:

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



Figure 1

- **A portable locking pouch** for you to keep a small supply of oral transmucosal fentanyl citrate nearby. The rest of your oral transmucosal fentanyl citrate 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).

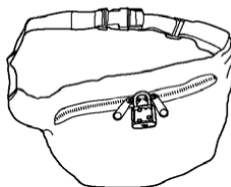


Figure 2

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



Figure 3

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

How should I dispose of oral transmucosal fentanyl citrate units when they are no longer needed?

Disposing of oral transmucosal fentanyl citrate units after use:

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

After you have finished the oral transmucosal fentanyl citrate 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 oral transmucosal fentanyl citrate unit after you have finished:

- Place the used oral transmucosal fentanyl citrate 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).

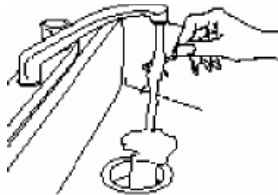


Figure 4

Temporary Storage of Used Oral Transmucosal Fentanyl Citrate Units:

- If you did not finish the entire oral transmucosal fentanyl citrate unit and you cannot dissolve the medicine under hot running water right away, put the used oral transmucosal fentanyl citrate unit in the temporary storage bottle that you received in the oral transmucosal fentanyl citrate Child Safety Kit. Place the oral transmucosal fentanyl citrate unit into the bottle and secure the cap. **Never leave unused or partially used oral transmucosal fentanyl citrate units where children or pets can get to them** (See Figure 5).



Figure 5

Disposing of Used Oral Transmucosal Fentanyl Citrate Units from the Temporary Storage Bottle:

You must dispose of all used oral transmucosal fentanyl citrate 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 oral transmucosal fentanyl citrate unit from the temporary storage bottle. Hold the oral transmucosal fentanyl citrate 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 oral transmucosal fentanyl citrate 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 oral transmucosal fentanyl citrate units, oral transmucosal fentanyl citrate handles, or blister packages down the toilet.

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

1. Remove all oral transmucosal fentanyl citrate from the locked storage space (See Figure 7).

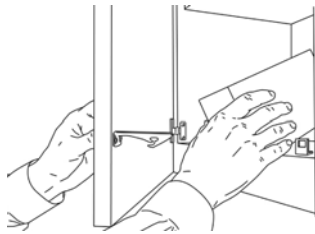


Figure 7

2. Remove one oral transmucosal fentanyl citrate 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).

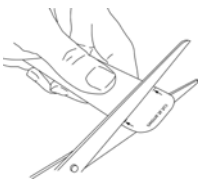


Figure 8A



Figure 8B

3. Hold oral transmucosal fentanyl citrate 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).

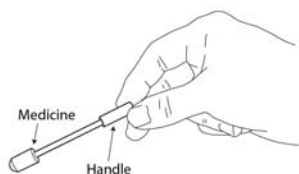


Figure 9A

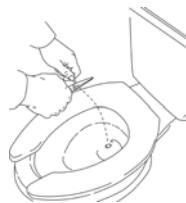


Figure 9B

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

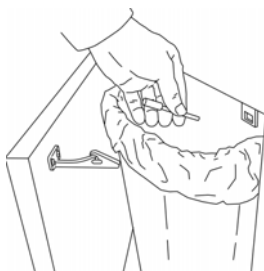


Figure 10

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



Figure 11

- Do not flush entire unused oral transmucosal fentanyl citrate units, oral transmucosal fentanyl citrate handles, or blister packages down the toilet.

If you need help with the disposal of oral transmucosal fentanyl citrate, call SpecGx LLC, Product Monitoring at 1-800-778-7898, or call your local Drug Enforcement Agency (DEA) office.

General information about oral transmucosal fentanyl citrate

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

This Medication Guide summarizes the most important information about oral transmucosal fentanyl citrate. If you would like more information, talk with your healthcare provider or pharmacist. You can ask your pharmacist or healthcare provider for information about oral transmucosal fentanyl citrate 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?

Active Ingredient: fentanyl citrate

Inactive Ingredients: Raspberry flavor, citric acid, confectioners sugar, dextrans, magnesium stearate, dibasic sodium phosphate, modified food starch, ethanol, water, purified shellac, propylene glycol, FD&C blue no. 1, ammonium hydroxide.

Patient Instructions for Use

Before you use oral transmucosal fentanyl citrate, 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 oral transmucosal fentanyl citrate the right way. Ask your healthcare provider or pharmacist if you have any questions about the right way to use oral transmucosal fentanyl citrate.

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

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



Figure 12

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

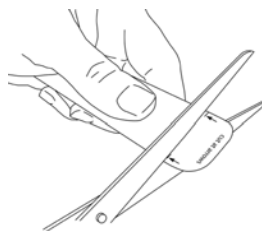


Figure 13A



Figure 13B

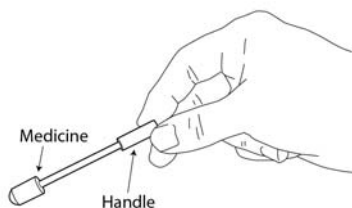


Figure 14

1. Place the medicine end of the oral transmucosal fentanyl citrate unit in your mouth between your cheeks and gums and actively suck on the medicine.
2. Move the medicine end of the oral transmucosal fentanyl citrate 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 oral transmucosal fentanyl citrate unit completely over 15 minutes to get the most relief. If you finish oral transmucosal fentanyl citrate too quickly, you will swallow more of the medicine and get less relief.

5. **Do not bite or chew oral transmucosal fentanyl citrate. You will get less relief for your breakthrough cancer pain.**
- If you cannot finish all of the medicine on the oral transmucosal fentanyl citrate unit and cannot dissolve the medicine under hot tap water right away, immediately put the oral transmucosal fentanyl citrate unit in the temporary storage bottle for safe keeping (See Figure 16).
 - Place the oral transmucosal fentanyl citrate unit into the bottle and secure the cap. You must properly dispose of the oral transmucosal fentanyl citrate unit as soon as you can.



Figure 16

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

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