

Medication Guide

Oral Transmucosal Fentanyl Citrate CII

(or' el • tranz mu-kō' s'l • fēn' tā-nīl • sīt' rāt)

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

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?

1. Oral transmucosal fentanyl citrate 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 oral transmucosal fentanyl citrate that is different than other fentanyl containing medicines you may have been taking. Do not substitute oral transmucosal fentanyl citrate for other fentanyl medicines without talking with your doctor.

What is oral transmucosal fentanyl citrate?

• Oral transmucosal fentanyl citrate is a prescription medicine that contains the medicine fentanyl. Oral transmucosal fentanyl citrate 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.

Oral transmucosal fentanyl citrate 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. Oral transmucosal fentanyl citrate 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 oral transmucosal fentanyl citrate if you are not opioid tolerant.

• You must stay under your doctor's care while taking oral transmucosal fentanyl citrate.

• Oral transmucosal fentanyl citrate must not be used for short-term pain from injuries and surgery.

• Prevent theft and misuse. Keep oral transmucosal fentanyl citrate 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 oral transmucosal fentanyl citrate 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?

Do Not Take oral transmucosal fentanyl citrate if you:

• are not already taking other opioid pain medicines for your constant (around-the-clock) cancer pain. **Never use oral transmucosal fentanyl citrate 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 oral transmucosal fentanyl citrate. The active ingredient in oral transmucosal fentanyl citrate is fentanyl. See the end of this Medication Guide for a complete list of ingredients in oral transmucosal fentanyl citrate.

What should I tell my doctor before I start taking oral transmucosal fentanyl citrate?

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 oral transmucosal fentanyl citrate unit contains about 1/2 teaspoon (2 grams) of sugar.

Tell your doctor if you are:

• pregnant or planning to become pregnant. Oral transmucosal fentanyl citrate may harm your unborn baby.



SPECIMEN

• **breast feeding.** Fentanyl passes through your breast milk and it can cause serious harm to your baby. You should not use oral transmucosal fentanyl citrate 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 oral transmucosal fentanyl citrate. Sometimes, the doses of certain medicines and oral transmucosal fentanyl citrate need to be changed if used together. Do not take any medicine while using oral transmucosal fentanyl citrate until you have talked to your doctor. Your doctor will tell you if it is safe to take other medicines while you are using oral transmucosal fentanyl citrate. 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?

• Use oral transmucosal fentanyl citrate exactly as prescribed. Do not take oral transmucosal fentanyl citrate more often than prescribed. Talk to your doctor about your pain. Your doctor can decide if your dose of oral transmucosal fentanyl citrate needs to be changed.

• Each unit of oral transmucosal fentanyl citrate is sealed in its own blister package.

• Do not open the blister package until you are ready to use oral transmucosal fentanyl citrate.

• When you are ready to use oral transmucosal fentanyl citrate, cut open the package using scissors and remove the oral transmucosal fentanyl citrate unit.



• Place oral transmucosal fentanyl citrate in your mouth between your cheeks and gums and actively suck on the medicine.



• Move oral transmucosal fentanyl citrate around in your mouth, especially along your cheeks.

• Twirl the handle often.

• Finish the oral transmucosal fentanyl citrate 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 oral transmucosal fentanyl citrate. You will get less relief for your breakthrough 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.

• 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. Dispose of oral transmucosal fentanyl citrate right away or put it in the temporary storage bottle in the welcome kit for later disposal.

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

• If you take too much oral transmucosal fentanyl citrate or overdose, call 911 or your local emergency number for help.

How should I dispose of oral transmucosal fentanyl citrate 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. Please follow these directions to dispose of the handle:

1. Once 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.
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 oral transmucosal fentanyl citrate unit and you cannot dissolve the medicine under hot running water right away, put the oral transmucosal fentanyl citrate in the temporary storage bottle that you received in the oral transmucosal fentanyl citrate welcome kit for safe keeping. Place the oral transmucosal fentanyl citrate unit into the bottle. **Never leave unused or partially used oral transmucosal fentanyl citrate 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 oral transmucosal fentanyl citrate units, oral transmucosal fentanyl citrate handles, or blister packages down the toilet.

What should I avoid while taking oral transmucosal fentanyl citrate?

• Do not drive, operate heavy machinery, or do other dangerous activities until you know how oral transmucosal fentanyl citrate affects how alert you are. Oral transmucosal fentanyl citrate can make you sleepy. Ask your doctor when it is okay to do these activities.

• Do not drink alcohol while using oral transmucosal fentanyl citrate. It can increase your chance of getting dangerous side effects.

• Do not take any medicine while using oral transmucosal fentanyl citrate until you have talked to your doctor. Your doctor will tell you if it is safe to take other medicines while you are using oral transmucosal fentanyl citrate. Be especially careful about medicines that make you sleepy such as other pain medicines, antidepressant medicines, sleeping pills, anxiety medicines, antihistamines, or tranquilizers.

What are the possible or reasonably likely side effects of oral transmucosal fentanyl citrate?

• Oral transmucosal fentanyl citrate 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 oral transmucosal fentanyl citrate?"

• 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) 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.

• Oral transmucosal fentanyl citrate can cause your blood pressure to drop. This can make you feel dizzy if you get up too fast from sitting or lying down.

• Oral transmucosal fentanyl citrate can cause physical dependence. Do not stop taking oral transmucosal fentanyl citrate 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 oral transmucosal fentanyl citrate. 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 oral transmucosal fentanyl citrate 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 oral transmucosal fentanyl citrate 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 oral transmucosal fentanyl citrate.

Oral transmucosal fentanyl citrate contains sugar. Cavities and tooth decay have occurred in patients taking oral transmucosal fentanyl citrate. When taking oral transmucosal fentanyl citrate, 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 oral transmucosal fentanyl citrate. For a complete list, ask your doctor.

How should I store oral transmucosal fentanyl citrate?

• Keep oral transmucosal fentanyl citrate 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 oral transmucosal fentanyl citrate, get emergency help right away.

• Oral transmucosal fentanyl citrate is supplied in single sealed child-resistant blister packages. Store oral transmucosal fentanyl citrate at room temperature, 59° to 86°F (15° to 30°C) until ready to use.

• Always keep oral transmucosal fentanyl citrate in a secure place to protect from theft.

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

• Dispose of any unopened oral transmucosal fentanyl citrate units remaining from a prescription as soon as they are no longer needed.

• If you are no longer using oral transmucosal fentanyl citrate or if you have unused oral transmucosal fentanyl citrate in your home, please follow these steps to dispose of the oral transmucosal fentanyl citrate as soon as possible.

1. Remove all oral transmucosal fentanyl citrate from the locked storage space.

2. Remove one oral transmucosal fentanyl citrate unit from its blister package using scissors, and 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 steps 2, 3, and 4 for each oral transmucosal fentanyl citrate.

6. Flush the toilet twice after 5 oral transmucosal fentanyl citrate units have been cut. Do not flush more than 5 oral transmucosal fentanyl citrate units at a time.

• 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 disposal of oral transmucosal fentanyl citrate, call Mallinckrodt Inc., Product Monitoring at 1-800-778-7898.

General Information About the Safe and Effective Use of 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 doctor. You can also ask your pharmacist or doctor for information about oral transmucosal fentanyl citrate that is written for healthcare professionals. You can also call Mallinckrodt Inc., at 1-800-778-7898.

What are the ingredients of oral transmucosal fentanyl citrate?

Active Ingredient: fentanyl citrate

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

How do I use the oral transmucosal fentanyl citrate welcome kit?

• You can use the oral transmucosal fentanyl citrate welcome 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 welcome kit to protect the children in your home.

• If you were not offered a welcome kit when you received your medicine, call Mallinckrodt Pharmaceutical Welcome Kit Request Line at 1-800-223-1499 to request one.

The oral transmucosal fentanyl citrate welcome kit contains:

• A child-resistant lock for you to secure the storage space where you keep oral transmucosal fentanyl citrate and any other medicines at home.

• A portable locking pouch for you to keep a small supply of oral transmucosal fentanyl citrate nearby for your immediate use. The rest of your oral transmucosal fentanyl citrate 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 oral transmucosal fentanyl citrate unit and cannot immediately dissolve the medicine under hot tap water, immediately put the oral transmucosal fentanyl citrate unit in the temporary storage bottle for safe keeping.



• Place the oral transmucosal fentanyl citrate unit into the bottle. You must properly dispose of the oral transmucosal fentanyl citrate unit as soon as you can.

• See "How should I dispose of unopened oral transmucosal fentanyl citrate units when they are no longer needed?" for proper disposal of oral transmucosal fentanyl citrate.

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

Manufactured by:
Mallinckrodt Inc.
Hazelwood, MO 63042

Printed in U.S.A.

tyco
Healthcare

Rev 061808

Mallinckrodt