Fentanyl Buccal Tablets (Fentora®)

**Pronounced:** FEN-ta-nil BUK-al

**Classification:** Opioid

**About Fentanyl Buccal Tablets (Fentora®)**

Opioids are the strongest form of medication used to treat pain. Opioids work by attaching to opioid receptors, which are found in many areas of the body, including the brain, spinal cord and gastrointestinal tract. An opioid attaches to the receptor, which reduces the transmission of pain messages to the brain, reducing pain. Opioids are used to treat moderate to severe pain that is not well managed with other pain medications. They do not treat the underlying cause of the pain. If cancer is causing the pain, the cancer treatment is aimed at reducing the pain.

There are several different ways to take fentanyl. Fentanyl buccal tablets are a fast acting form of fentanyl used to treat breakthrough pain. Breakthrough pain is pain that comes on quickly and occurs intermittently (or “flares”), despite the regular use of long-acting pain medications. When this pain occurs, a fast-acting pain medication is needed to ease the pain.

**How to Take Fentanyl Buccal Tablets**

Fentanyl tablets are placed above a rear molar tooth, between your cheek and gum (buccal). It can also be placed under your tongue. A gentle bubbling sensation will be felt as the tablet dissolves. The medication should not be broken or chewed. It may take 15 to 25 minutes for the pill to completely dissolve. If there is any tablet remaining after 30 minutes, it can be swallowed with a glass of water. Do not eat or drink anything until the tablet has completely dissolved.

Your physician will tell you the dose that is right for you. If your pain is not relieved in 30 minutes and it has been approved by your provider, one additional fentanyl buccal tablet (of the same dose) can be taken.

It is important to make sure you are taking the correct amount of medication every time. Before every dose, check that what you are taking matches what you have been prescribed. You should also not replace one type of fentanyl for another. Take only what you have been prescribed.

This medication can interact with other medications that depress the central nervous system like barbituates (including phenobarbital), tranquilizers (including Haldol®, Librium® and Xanax®), other narcotics and general anesthetics. The blood levels of this medication can be affected by certain foods and medications, so they may require dose adjustment or should be avoided. These include: grapefruit, grapefruit juice, verapamil, ketoconazole, rifampin, phenytoin, St. John’s wort, and modafanil. Be sure to tell your healthcare provider about all medications and supplements you take.

DO NOT share this medication or give it to someone else, as severe breathing problems and death can occur.

This medication can cause dizziness, sleepiness and confusion. You should not drive or operate machinery while taking this medication until you know how it will effect you.

**Storage and Handling**

Store this medication at room temperature in the original container. Due to the risk of diversion (someone else taking your narcotic medication to obtain a high, rather than for symptom relief), you may want to consider keeping your medication in a lock box or other secure location. Ask your oncology team where to return any unused medication for disposal. Do not flush down the toilet or throw in the trash. Keep this medication out of reach of children and pets.
To prevent someone accidentally taking this medication, it should be disposed of when no longer needed through a medicine take-back program or by dropping them off at a DEA-authorized collector. For locations near you, check www.dea.org. Ask your pharmacist or care team for assistance in disposal of unused medications. If you cannot use these options, you can flush these medicines down the sink or toilet as soon as they are no longer needed.

Where do I get this medication?

Fentanyl buccal tablets are available through retail and mail order pharmacies. Your oncology team will work with your prescription drug plan to identify an in-network pharmacy for medication distribution. Mail order deliveries must be hand delivered and signed for. This medication cannot be "called in" or electronically prescribed to your local pharmacy; you must provide the original prescription to the pharmacist. Many pharmacies do not keep this medication in stock, but will order it for you. There may be a delay in availability, so plan prescription refills accordingly.

This medication requires the patient, prescriber and pharmacist enroll in the TIRF-REMS program (risk evaluation and mediation program). The purpose of this program is to provide education to patients, caregivers and providers to reduce the risk of misuse, abuse, addiction and overdose. You or your caregiver will be required to read and sign a patient-prescriber agreement form before you can start treatment with this medication.

Insurance Information

This medication may be covered under your prescription drug plan. Patient assistance may be available to qualifying individuals without prescription drug coverage. Co-pay cards, which reduce the patient's co-pay responsibility for eligible commercially (non-government sponsored) insured patients, may be offered by the manufacturer. Your insurance company may require you to utilize other narcotic pain medications prior to approving a prescription for fentanyl buccal tablets. This is called step therapy. Due to risk for diversion and misuse, the quantity of medication you receive may be limited to a 2 week or 1 month supply.

Possible Side Effects of Fentanyl Buccal Tablets

There are a number of things you can do to manage the side effects of fentanyl buccal tablets. Talk to your care team about these recommendations. They can help you decide what will work best for you. These are some of the most common or important side effects:

**Slowed Breathing or Low Blood Pressure**

You may experience low blood pressure or slowed breathing while taking an opioid pain medication. This usually only occurs when the dose of medication is too high or it is increased too quickly. This rarely happens to patients who have been taking opioid medications for a long time.

These side effects can also result from an overdose of opioids. If you suspect that you or someone you know has taken an overdose of opioids, call 911 immediately. If you feel extremely tired, lightheaded, dizzy, sweaty, nauseated, or short of breath, you need to seek care immediately. Sometimes patients who have taken too much opioid medication will be so sleepy that they can't be awakened or aroused. These side effects are emergency situations. If any of these symptoms occur, you should seek emergency medical attention.

**Sleepiness (Somnolence)**

Feeling sleepy, drowsy or lightheaded may accompany the use of opioid pain medication. Some people just don't "feel like themselves" on these medications. Avoid driving or any other potentially dangerous tasks that require your concentration and a clear head until you feel normal again. Avoid alcohol or other sedatives while using these medications unless they are specifically prescribed by your care team. Most people will begin to feel like themselves after a few days on the medications. If you continue to feel "out of it" after a couple of days, talk to your healthcare provider about adjusting your dosages.

**Nausea and/or Vomiting**

Nausea, with or without vomiting, can be a side effect of opioid pain medications. For some patients it lasts just a few days to weeks after starting the medication, but for some it is a long-term side effect. Nausea and vomiting can interfere with pain...
management if the nausea and/or vomiting affects the patient's ability to take the medication. You may find that eating or not eating when taking this medication may be helpful for you. Talk to your healthcare team so they can prescribe medications to help you manage nausea and vomiting.

**Constipation Caused by Pain Medications**

Constipation is a very common side effect of pain medications that continues as long as you are taking the medications. This side effect can often be managed well with the following preventative measures:

- Drinking 8-10 glasses of water a day. Warm or hot fluids can be helpful.
- Increasing physical activity when possible.
- Attempting a bowel movement at the same time each day.
- Eating plenty of fruits and vegetables.
  - Four ounces of prune juice or 3-4 dried prunes/plums can help promote bowel movements.
  - However, high fiber foods (ex. bran flakes, high fiber cereals) and fiber supplements (such as Metamucil) can actually make constipation from pain medications worse and should be avoided.

Your care team may recommend a bowel regimen, using stool softeners and/or laxatives, to prevent or treat constipation. Stool softeners (such as docusate sodium or Colace) work by bringing water into the stool, making it softer and easier to pass. A stimulant or laxative (such as Dulcolax (bisacodyl) or Senakot (senna)) works by stimulating the movements of stool through the bowel. Your provider may recommend Miralax (Polyethylene glycol 3350), which is an osmotic laxative. It works by causing water to be retained in the stool, softening the stool so it is easier to pass. These medications can be taken together. Untreated constipation can lead to a bowel blockage, so be sure to notify your healthcare team if you do not have a bowel movement for 3 or more days.

**Concerns About Addiction, Tolerance, and Dependence**

Many people who are prescribed opioid pain relievers are worried that they may become addicted to these medications. This fear stems from the fact that opioid medications can cause euphoria and pleasure when used by people who are not in pain. However, when these medications are used to treat physical pain, it is unlikely that patients will become addicted to them. Addiction is a psychological need for the drug that very rarely affects people who take opioids for pain control. People addicted to opioids use them for the purpose of getting "high". These people also crave opioids, lack control over their use, and will continue to use opioids despite knowing they are causing them harm. People experiencing pain use opioids to relieve their pain.

A person on long-term opioids may stop getting proper pain relief after taking these medications for a while. This phenomenon is called tolerance. As patients develop tolerance, they will need higher doses to get good pain relief. Tolerance is a completely normal aspect of taking opioid pain medications, and is nothing to be concerned about. The point of using these medications is to keep pain well controlled, and the exact doses that a patient requires are not important as long as they can be kept comfortable. If you think you need to change the dose, work with your healthcare team to find the right dose to make you comfortable. Do not try to change the dose on your own, as this may cause unwanted side effects.

As a person takes regular doses of opioids, for as little as a week, their bodies will begin to adapt to the medications. This causes tolerance, but it can also cause dependence. Dependence means that the body "gets used to" the opioids. Dependence DOES NOT equal addiction. Dependence is a natural, physical phenomenon that happens to everyone on long-term opioid therapy. The important thing to know about dependence is that once a patient becomes dependent on opioids, they will feel very sick if they stop the medication abruptly. This is called withdrawal and the symptoms it causes can start within 2 days of abruptly stopping opioids and may last up to 2 weeks. Withdrawal is preventable if you lower the opioid dose slowly, generally over a week or so, with the help and guidance of your health care team. The exact amount of time to wean varies based on dose, how long you’ve been taking them, and some other individual factors. It is important to remember that dependence is normal, and happens to everyone who takes opioids for a long period of time. Talk to your provider if you have any concerns.

**Less common, but important side effects can include:**

- **Serotonin Syndrome:** This medication can cause a high level of serotonin in your body, which in rare cases, can lead to...
serotonin syndrome. Symptoms can include shivering, agitation, diarrhea, nausea and vomiting, fever, seizures, and changes in muscle function. Symptoms can arise hours to days after continued use, but can also occur later. This is a serious side effect and you should contact your care provider immediately if you have any of these side effects.

- **Adrenal Insufficiency**: Adrenal insufficiency (inadequate function of the adrenal gland) is a rare but serious side effect of taking this medication. It most often occurs after taking the medication for one month or longer. Symptoms are not very specific, but can include nausea, vomiting, anorexia, fatigue, weakness, dizziness, and low blood pressure. It is important to contact your care provider if you experience any of these side effects.

**Reproductive Concerns**

Chronic exposure of an unborn child to this medication could result in the child being born small and/or early, or having symptoms of withdrawal (including respiratory distress, behavioral changes and seizures) after birth. Effective birth control should be used while on this medication. Even if your menstrual cycle stops or you believe you are not producing sperm, you could still be fertile and conceive. You should not breastfeed while receiving this medication as it is passed through a mother’s milk.