

Medication Guide

ABSTRAL® (AB-stral) CII
(fentanyl)
Sublingual tablets

100 mcg, 200 mcg, 300 mcg, 400 mcg, 600 mcg, 800 mcg

IMPORTANT:

Do not use ABSTRAL unless you are regularly using another opioid pain medicine around-the-clock for your cancer pain and your body is used to these medicines (this means that you are opioid tolerant).

Keep ABSTRAL in a safe place away from children.

Get emergency medical help right away if:

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

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

Read this Medication Guide completely before you start taking ABSTRAL, 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. Be sure to share this important information with members of your household and other caregivers.

What is the most important information I should know about ABSTRAL?

ABSTRAL can cause life-threatening breathing problems which can lead to death.

1. **Do not take ABSTRAL 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** taking ABSTRAL. You may no longer be opioid tolerant. Talk to your healthcare provider about how to treat your pain.
3. **Take ABSTRAL exactly as prescribed by your healthcare provider.**
 - You must not take more than 2 doses of ABSTRAL for each episode of breakthrough cancer pain.
 - You must wait two hours before treating a new episode of breakthrough pain with ABSTRAL. **See the Medication Guide section “How should I take ABSTRAL?” and the Patient Instructions for Use at the end of this Medication Guide for detailed information about how to take ABSTRAL the right way.**
4. **Do not switch from ABSTRAL to other medicines that contain fentanyl without talking with your healthcare provider.** The amount of fentanyl in a dose of ABSTRAL is not the same as the amount of fentanyl in other medicines that contain fentanyl. Your healthcare provider will prescribe a starting dose of ABSTRAL that may be different than other fentanyl containing medicines you may have been taking.
5. **Do not take ABSTRAL 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 ABSTRAL to anyone else**, even if they have the same symptoms you have. It may harm them or even cause death.

ABSTRAL 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 ABSTRAL in a safe place** to protect it from being stolen. ABSTRAL 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. ABSTRAL is available only through a program called the TIRF (Transmucosal Immediate-Release Fentanyl) REMS (Risk Evaluation and Mitigation Strategy) Access program. To receive ABSTRAL, you must:

- talk to your healthcare provider
- understand the benefits and risks of ABSTRAL
- agree to all of the instructions

- sign the Patient-Prescriber Agreement form

What is ABSTRAL?

- ABSTRAL is a prescription medicine that contains the medicine fentanyl.
- ABSTRAL is used to manage breakthrough pain in adults with cancer (18 years of age and older) who are already routinely taking other opioid pain medicines around-the-clock for cancer pain.
- ABSTRAL 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 ABSTRAL if you are not opioid tolerant.
- ABSTRAL is a small tablet that is placed on the floor of the mouth under your tongue (sublingual) and allowed to dissolve.
- You must stay under your healthcare provider's care while taking ABSTRAL.
- ABSTRAL is only:
 - available through the TIRF REMS Access program
 - given to people who are opioid tolerant

It is not known if ABSTRAL is safe and effective in children under 18 years of age.

Who should not take ABSTRAL?

Do not take ABSTRAL:

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

What should I tell my healthcare provider before taking ABSTRAL?

Before taking ABSTRAL, 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 health 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 problem or addiction problem, or a family history of a drug abuse problem or addiction problem
- have any other medical conditions
- are pregnant or plan to become pregnant. ABSTRAL may cause serious harm to your unborn baby.
- are breastfeeding or plan to breastfeed. ABSTRAL can pass into your breast milk. It can cause serious harm to your baby. You should not use ABSTRAL 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 ABSTRAL. Sometimes, the doses of certain medicines and ABSTRAL may need to be changed if used together.

- **Do not take any medicine while using ABSTRAL 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 ABSTRAL.
- 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 take ABSTRAL?

Before you can begin to take ABSTRAL:

- Your healthcare provider will explain the TIRF REMS Access program to you.
- You will sign the TIRF REMS Access program Patient-Prescriber Agreement form.
- ABSTRAL 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 ABSTRAL prescription filled.

Taking ABSTRAL:

- **Take ABSTRAL exactly as prescribed. Do not take ABSTRAL more often than prescribed.**
- **If you notice that your tablets are a different shape or color,** be sure to check with your pharmacist to make sure you have the right strength of medicine.
- **Do not** suck, chew or swallow the tablet.
- **See the detailed Patient Instructions for Use at the end of this Medication Guide for information about how to take ABSTRAL the right way.**
- Your healthcare provider will change the dose until you and your healthcare provider find the right dose for you.
- You must not use more than 2 doses of ABSTRAL for each episode of breakthrough cancer pain:
 - Take 1 dose for an episode of breakthrough cancer pain.
 - If your breakthrough pain does not get better within 30 minutes after taking the first dose of ABSTRAL, you can take 1 more dose of ABSTRAL as instructed by your healthcare provider.
 - If your breakthrough pain does not get better after the second dose of ABSTRAL, call your healthcare provider for instructions. **Do not take another dose of ABSTRAL at this time.**
- Wait at least 2 hours before treating a new episode of breakthrough cancer pain with ABSTRAL:
 - If you only need to take 1 dose of ABSTRAL for an episode of breakthrough pain, you must wait 2 hours from the time of that dose to take a dose of ABSTRAL for a **new** episode of breakthrough pain
 - If you need to take 2 doses of ABSTRAL for an episode of breakthrough pain, you must wait 2 hours after the second dose to take a dose of ABSTRAL for a **new** episode of breakthrough pain.
- It is important for you to keep taking your around-the-clock opioid pain medicine while taking ABSTRAL.
- Talk to your healthcare provider if your dose of ABSTRAL does not relieve your breakthrough cancer pain. Your healthcare provider will decide if your dose of ABSTRAL 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 take too much ABSTRAL 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 taking ABSTRAL?

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

What are the possible side effects of ABSTRAL?

ABSTRAL 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 ABSTRAL?”
 - **Call your healthcare provider or get emergency medical help right away if you:**
 - have trouble breathing
 - have drowsiness with slowed breathing
 - have shallow breathing (little chest movement with breathing)
 - feel faint, very dizzy, confused, or have other unusual symptomsThese symptoms can be a sign that you have taken too much ABSTRAL 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 take any more ABSTRAL 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 ABSTRAL 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 ABSTRAL are:

- nausea
- sleepiness
- headache

Constipation (not often enough or hard bowel movements) is a very common side effect of pain medicines (opioids) including ABSTRAL 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 ABSTRAL.

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 ABSTRAL. For more information, ask your healthcare provider or pharmacist.

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

How should I store ABSTRAL?

- **Always keep ABSTRAL in a safe place away from children and from anyone for whom it has not been prescribed.** Protect ABSTRAL from theft.
- Store ABSTRAL at room temperature, 59°F to 86°F (15°C to 30°C) until ready to use.
- Keep ABSTRAL in the original blister unit. Do not remove ABSTRAL tablets from their blister packaging for storage in a temporary container, such as a pillbox.

How should I dispose of unopened ABSTRAL tablets when they are no longer needed?

- Dispose of any unopened ABSTRAL units remaining from a prescription as soon as you no longer need them:
 - remove the tablets from the blister cards and flush them down the toilet.
- Do not flush the ABSTRAL blister cards, units or cartons down the toilet.
- If you need help with disposal of ABSTRAL, call ProStrakan, Inc., at 1-888-227-8725 or call your local Drug Enforcement Agency (DEA) office.

General information about ABSTRAL

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

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

Active Ingredient: fentanyl citrate

Inactive Ingredients: croscarmellose sodium, magnesium stearate, mannitol, and silicified microcrystalline cellulose.

Patient Instructions for Use

Before you take ABSTRAL, 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 take ABSTRAL the right way. Ask your healthcare provider or pharmacist if you have questions about the right way to take ABSTRAL.

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

- If your mouth is dry, take a sip of water to moisten it. Spit out or swallow the water. Dry your hands if they are wet before you handle ABSTRAL tablets.
- ABSTRAL comes in a blister card with 4 blister units. Each blister unit contains an ABSTRAL tablet. It is important that the tablet stays sealed in the blister unit until you are ready to use it.
- When you are ready to take an ABSTRAL tablet, pull apart 1 of the blister units from the blister card by tearing along the dotted lines (perforations) until it is fully separated. (See Figures 1 and 2)

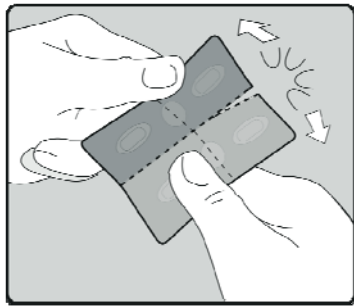


Figure 1

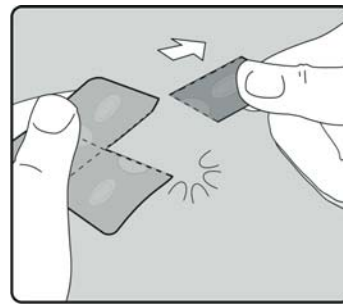


Figure 2

- When the blister unit is fully separated, peel back the foil starting at the unsealed area where indicated. Gently remove the tablet. **Do not** try to push ABSTRAL tablets through the foil. This will damage the tablet. (See Figures 3 and 4)

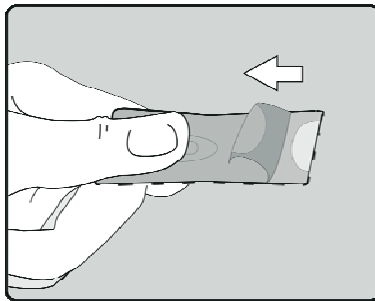


Figure 3

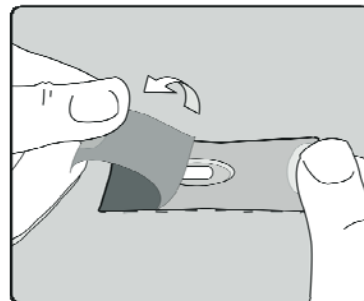


Figure 4

- As soon as you remove the ABSTRAL tablet from the blister unit:
 - place it on the floor of your mouth, under your tongue, as far back as you can (See Figures 5, 6, and 7).

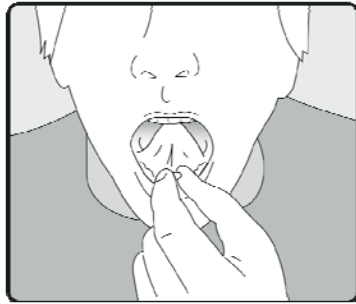


Figure 5

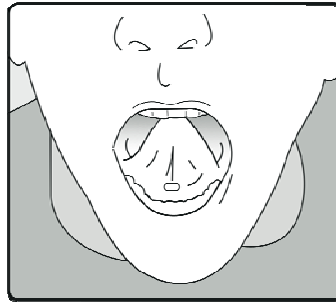


Figure 6

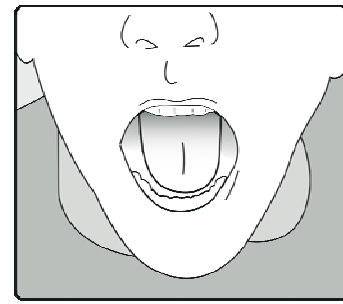


Figure 7

- If more than 1 tablet is required, spread them around the floor of your mouth under your tongue.
- Let the tablet dissolve completely.
ABSTRAL dissolves under your tongue and will be absorbed by your body to help provide relief for your breakthrough cancer pain.
- **Do not suck, chew or swallow the tablet.**
- You should not drink or eat anything until the tablet has completely dissolved under your tongue and you can no longer feel it in your mouth.

Manufactured by:
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Lincoln, NE 68517

Manufactured for:
ProStrakan Inc.,
Bedminster, NJ 07921

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