

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

IMPORTANT:

Do not use ABSTRAL 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 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.

ABSTRAL is:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage breakthrough pain in adults with cancer 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.
- 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 ABSTRAL:

- **Get emergency help right away if you take too much ABSTRAL (overdose).** When you first start taking ABSTRAL, when your dose is changed, or if you take too much (overdose), serious life-threatening breathing problems that can lead to death may occur.
- Taking ABSTRAL with other opioid 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 ABSTRAL. They could die from taking it. Store ABSTRAL away from children and in a safe place to prevent stealing or abuse. Selling or giving away ABSTRAL is against the law.
- If you stop taking your around-the-clock opioid pain medicine for your cancer pain, **you must stop** using ABSTRAL. You may no longer be opioid tolerant. Talk to your healthcare provider about how to treat your pain.
- ABSTRAL is available only through a program called the **Transmucosal Immediate-Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS) 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

- 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.
- Be very careful about taking other medicines that may make you sleepy, such as other pain medicines, anti-depressant medicines, 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.

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 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 ABSTRAL. See the end of this Medication Guide for a complete list of ingredients in ABSTRAL.
- 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 ABSTRAL, 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
- 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
- abuse of street or prescription drugs, alcohol addiction, or mental health problems

Tell your healthcare provider if you are:

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

When taking ABSTRAL:

- Do not change your dose. Take ABSTRAL 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 Instructions for Use at the end of this Medication Guide for information about how to use ABSTRAL.**
- **Use ABSTRAL tablets whole.**
- **Do not crush, split, suck, or chew ABSTRAL tablets, or swallow the tablets whole. You will get less relief for your breakthrough cancer pain.**
- Wait 30 minutes after using ABSTRAL. If there is any of the ABSTRAL tablet left in your mouth, you may drink a glass of water to help you swallow the left over medicine.
- You must not use more than 2 doses of ABSTRAL for each episode of breakthrough cancer pain.
- Use **1** dose of ABSTRAL for an episode of breakthrough cancer pain.
- If your breakthrough cancer pain does not get better 30 minutes after taking the first dose of ABSTRAL, you can use **only 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 use another dose of ABSTRAL at this time.**
- Wait at least **4** 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 4 hours from the time of that dose to take a dose of ABSTRAL for a **new** episode of breakthrough pain.
- If you need to use 2 doses of ABSTRAL for an episode of breakthrough pain, you must wait 4 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 using 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 begin to feel dizzy, sick to your stomach, or very sleepy before the tablet is completely dissolved, rinse your mouth with water and spit the remaining pieces of the tablet into a sink or toilet right away. Rinse the sink or flush the toilet to dispose of any remaining tablet pieces.
- Do not stop taking ABSTRAL without talking to your healthcare provider.
- After you stop taking, or when ABSTRAL is no longer needed, see “**How should I dispose of unused ABSTRAL tablets when they are no longer needed?**” for proper disposal of ABSTRAL.
- **DO NOT** Drive or operate heavy machinery, until you know how ABSTRAL affects you. ABSTRAL 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 ABSTRAL may cause you to overdose and die.
- **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.

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 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)

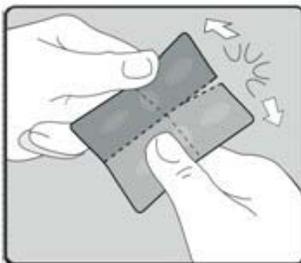


Figure 1

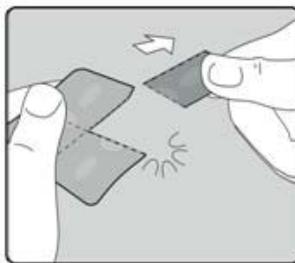


Figure 2

- 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)

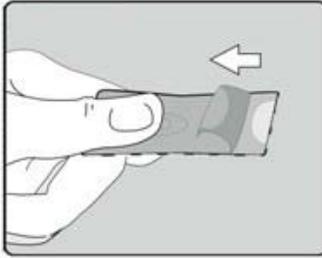


Figure 3

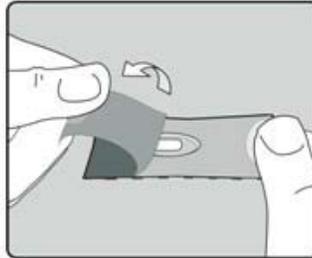


Figure 4

- 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

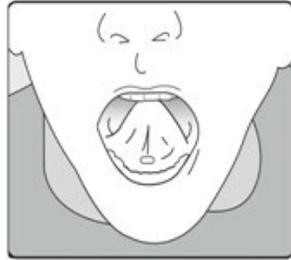


Figure 6



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:
Pharmaceutics International, Inc. Hunt Valley, MD 21031

Manufactured for:
Sentyln Therapeutics, Inc. Solana Beach, CA 92075

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