

Lazanda® (La-ZAN-da) CII

(fentanyl)

nasal spray

100 mcg, 400 mcg

IMPORTANT:

Do not use Lazanda 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). You can ask your healthcare provider if you are opioid tolerant.

Keep Lazanda in a safe place away from children.

Get emergency medical help right away if:

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

These are medical emergencies that can cause death.

Read this Medication Guide completely before you start taking Lazanda 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 Lazanda?

Lazanda can cause life-threatening breathing problems that can lead to death:

1. **Do not take Lazanda if you are not opioid tolerant.**
2. If you stop taking your around-the-clock opioid pain medicine for your cancer, **you must stop** taking Lazanda. You may no longer be opioid tolerant. Talk to your healthcare provider about how to treat your pain.
3. **Take Lazanda exactly as prescribed by your healthcare provider.**
 - You must not take more than **1** dose of Lazanda for each episode of breakthrough cancer pain.
 - You must wait two hours before treating a new episode of breakthrough cancer pain with Lazanda. **See the Medication Guide section “How should I use Lazanda?” and the “Instructions for Use” section at the end of this Medication Guide for detailed information about how to use Lazanda the right way.**
4. **Do not switch from Lazanda to other medicines that contain fentanyl without talking with your healthcare provider.** The amount of fentanyl in a dose of Lazanda is not the same as the amount of fentanyl in other medicines that contain fentanyl. Your

healthcare provider will prescribe a starting dose of Lazanda that may be different than other fentanyl-containing medicine you may have been taking.

5. **Do not** take Lazanda 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 Lazanda to anyone else**, even if they have the same symptoms you have. It may harm them or even cause death.

Lazanda 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 Lazanda in a safe place** to protect it from being stolen. Lazanda can be a target for people who abuse opioid (narcotic) medicines or street drugs.
- **Selling or giving away this medicine is against the law.**

Lazanda is available only through a program called the TIRF REMS ACCESS program. To receive Lazanda, you must:

- talk to your healthcare provider
- understand the benefits and risks of Lazanda
- agree to all of the instructions
- sign the Patient-Prescriber Agreement form

What is Lazanda®?

- Lazanda is a prescription medicine that contains the medicine fentanyl.
- Lazanda 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.
- Lazanda 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 Lazanda if you are not opioid tolerant.
- You must stay under your healthcare provider's care while taking Lazanda.
- Lazanda is a nasal spray. You use Lazanda by placing the nozzle attached to the bottle in your nostril and spraying. **See the Medication Guide section "How should I use Lazanda?"**
- Lazanda is only:
 - available through the TIRF REMS ACCESS program
 - given to people who are opioid tolerant

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

Who should not take Lazanda?

Do not take Lazanda:

- **if you are not opioid tolerant. Opioid tolerant means that you are already taking other opioid (narcotic) 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 fentanyl or any of the ingredients in Lazanda. See the end of this Medication Guide for a complete list of other ingredients in Lazanda.

What should I tell my healthcare provider before taking Lazanda?

Before taking Lazanda, 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 planning to become pregnant. Lazanda may cause serious harm to your unborn baby
- are breastfeeding or plan to breastfeed. Lazanda can pass into your breast milk. It can cause serious harm to your baby. Do not use Lazanda while breastfeeding

Tell your healthcare provider about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Some medicines may cause serious or life-threatening medical problems when taken with Lazanda. Sometimes, the doses of certain medicines and Lazanda need to be changed if used together.

- **Do not take any medicine while using Lazanda 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 Lazanda.
- Be very careful about taking other medicines that may make you sleepy, such as other pain medicines, anti-depressants, sleeping pills, anti-anxiety medicines, anti-histamines, 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 use Lazanda?

Before you can begin to use Lazanda:

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

Using Lazanda:

- **Use Lazanda exactly as your healthcare provider tells you to.** Do not use Lazanda more often than prescribed.
- See the “Instructions for Use” section at the end of this Medication Guide for detailed information about the right way to use and throw away (dispose of) Lazanda.
- Lazanda comes in 2 strengths. When you are first prescribed Lazanda, your healthcare provider will start you with the lower strength medicine, and will change the dose until you and your healthcare provider find the right dose for you. **Do not change your dose of Lazanda unless your healthcare provider tells you to.**
- The beginning dose of Lazanda is always **1** spray in **one** of your nostrils.
- **Always use 1 dose of Lazanda for an episode of breakthrough cancer pain exactly as your healthcare provider tells you to.** As your dose is adjusted, your healthcare provider will tell you whether your **dose of Lazanda is 1 or 2 sprays**:
 - **1** spray is given by spraying **1** time into **one** of your nostrils
 - **2** sprays are given by spraying **1** time into **each** nostril for a **total of 2 sprays**.

You must never use more than 2 sprays (1 spray in each nostril) for an episode of breakthrough pain.

- If an episode of breakthrough cancer pain continues for more than 30 minutes after you take a dose of Lazanda, follow your healthcare provider’s instructions about taking a short-acting opioid pain medicine to manage your pain.
- Wait at least 2 hours before treating a new episode of breakthrough cancer pain with Lazanda.
- It is important for you to keep taking your around-the-clock opioid pain medicine while using Lazanda.
- Talk to your healthcare provider if your dose of Lazanda does not relieve your breakthrough cancer pain. Your healthcare provider will decide if your dose of Lazanda 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.
- The Lazanda nasal spray pump provides a total of 8 full sprays. When there is a red number “8” in the counting window, you have used all the medicine in the bottle. You may still see medicine in the bottle, but there is not enough for a full dose. **Do not try to take more than 8 sprays from a bottle of Lazanda.**

- If you use too much Lazanda 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 using Lazanda?

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

What are the possible side effects of Lazanda?

1. **Breathing problems that can become life-threatening.** See “What is the most important information I should know about Lazanda?”

- **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 symptoms

These symptoms can be a sign that you have taken too much Lazanda 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 Lazanda 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 Lazanda 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.** The 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 problems.

The most common side effects of Lazanda are:

- vomiting
- nausea
- constipation
- dizziness

- o fever

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

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

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

How should I store Lazanda?

- **Always keep Lazanda in a safe place away from children and from anyone for whom it has not been prescribed.** Protect Lazanda from theft.
- Store Lazanda at up to 77°F (25°C). **Do not freeze Lazanda.**
- Lazanda comes in a clear glass bottle with an attached nasal spray pump and a protective cap.
- Store Lazanda in the child-resistant container that comes with it at all times except when you are using it. Store the Lazanda child-resistant container and pouch in the cardboard box when not in use.
- Keep Lazanda away from light.
- See the “Instructions for Use” section at the end of this Medication Guide for information about the right way to dispose of Lazanda when no longer needed.

General information about Lazanda

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

This Medication Guide summarizes the most important information about Lazanda. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about Lazanda that is written for healthcare professionals.

For more information about the TIRF REMS ACCESS program, go to www.tirfremssaccess.com or call 1-866-822-1483.

What are the ingredients in Lazanda?

Active ingredient: fentanyl citrate

Inactive ingredients: mannitol, pectin, phenylethyl alcohol, propylparaben, sucrose, water

Instructions for Use

Before you take Lazanda it is important that you read, understand, and follow the full Medication Guide, including these Instructions for Use. Ask your healthcare provider or pharmacist if you have any questions about the right way to prepare, use, or dispose of Lazanda. Wash your hands with soap and water before and after you use Lazanda.

What will I find in the Lazanda pack?

Each Lazanda pack contains a cardboard box that includes **(See Figure A)**:

- a Medication Guide (not shown)
- a disposal pouch **(See Figure B)**
- a child-resistant container, which holds 1 bottle of Lazanda.

Take the pouch and the Lazanda bottle in its child-resistant container out of the cardboard box when you are ready to use it. Keep the cardboard box and child-resistant container for storing your Lazanda. You will need to keep the pouch to safely dispose of any medicine left in the bottle.

Do not remove the plastic strip from the pouch until you are ready to seal it.

- Store the Lazanda bottle in the child-resistant container whenever it is not in use.

See the section “How should I store Lazanda?” for more information about storing Lazanda.

Preparing Lazanda for use

Before you use a new bottle of Lazanda for the first time, you will need to prime (prepare) the bottle. To prime the bottle:

1. Remove the cap from the child-resistant container. To do this, squeeze the raised tabs on the cap and twist the cap to remove **(See Figure C)**. Take the bottle of Lazanda out of the child-resistant container.
2. Remove the protective cap from the nozzle (tip) **(See Figure D)**.
3. Place the tip of the Lazanda bottle into the opening of the pouch. Hold the Lazanda bottle upright so that the spray goes into the pouch **(See Figure E)**.



Figure A

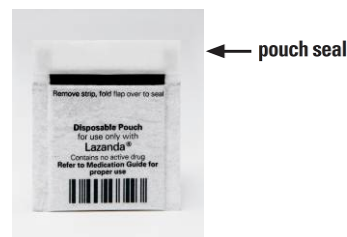


Figure B



Figure C



Figure D

Figure E

4. Look at the counting window. A new unused bottle of Lazanda will show 2 thin red lines in the counting window in the white plastic top on the bottle **(See Figure F)**.

- Firmly press on the grips and then release. You will hear a “click” and you will see 1 wide red bar in the counting window **(See Figure G)**.



Figure F



Figure G



Figure H



Figure I



Figure J

- Keep pressing and releasing the grips **3 more times** (for a total of 4 times). Each time, the red bar will become smaller until you see a green bar in the counting window **(See Figures H, I, J)**.

5. When you see the green bar, this means that Lazanda is ready for use **(See Figure K)**.

6. Remove the tip of the bottle from the pouch. Do not seal the pouch. Do not throw the pouch away.

7. If you are not going to take your medicine right away
- Replace the protective cap
 - Put the bottle in its child-resistant container. Put the child-resistant container and pouch in the cardboard box.
 - Store the box securely out of the reach of children and pets



Figure K

8. Wash your hands with soap and water.

Using Lazanda

1. Check to be sure that the Lazanda bottle is ready for use. If the bottle is ready for use, you will see either a green bar **(See Figure L)** or a number **(See Figure M)** in the counting window.



Figure L



Figure M

2. If you have a runny nose, blow your nose now.

3. Remove the protective cap from the nozzle (tip).

4. Sit up with your head upright and hold the Lazanda bottle with your thumb on the bottom of the bottle and your first and middle fingers on the finger grips **(See Figure N)**. Insert the tip a short distance (about ½ inch) into your nose, and point the tip toward the bridge of your nose. This will tilt the bottle slightly **(See Figure O)**.



Figure N



Figure O



Figure P

5. Close off the other nostril with 1 finger **(See Figure P)**.

6. Firmly press down on the finger grips until you hear a “click”.

7. Breathe in gently through your nose and out through your mouth 1 time after spraying. Do not sniff after spraying the medicine into your nose.
 - You may not feel the spray go into your nose. This is normal.
 - After you hear the click, you will see that the number in the counting window has increased by 1. This tells you that a spray has been given.
8. If your healthcare provider has prescribed a second spray, repeat steps 4 through 7, but use the other nostril.
9. After each spray, the number in the counting window will increase by 1. When you see a red number "8" in the counting window, the bottle is finished and you will no longer be able to get a full dose from it. You may still see medicine in the bottle, but there is not enough for a full dose. Do not try to take another dose of Lazanda from this bottle.
10. Stay sitting down for at least 1 minute after using Lazanda.
11. Avoid blowing your nose for at least 30 minutes after each spray.
12. Replace the protective cap on the tip of the bottle **(See Figure Q)**. Return the bottle to the child-resistant container after each use, and store securely out of the reach of children.



Figure Q

Disposing of Lazanda

Dispose of the Lazanda bottle when no longer needed:

- If you have used 8 sprays from a bottle, or
- If it has been 5 days since you last used the bottle, or
- If it has been 14 days since you primed (prepared) your bottle

Before you throw away the Lazanda bottle, you must empty all the remaining medicine into the pouch. This is to protect others, especially children, from harm.

Disposal of any unused Lazanda

If you can see a number, other than 8 in the counting window, you have NOT used all 8 sprays in the bottle. There are still doses of Lazanda in the bottle.

- You must empty the remaining doses of Lazanda from the bottle
- Put tip in pouch and press and release the grips **(See Figure R)** until the red number "8" appears in the counting window **(See Figure S)**.

When you see the number "8" in the counting window (See Figure S), there is still medicine in the bottle that you must spray in the pouch.



Figure R



Figure S

- Put the tip into the pouch. **(See Figure R)**
- Press and release the grips a total of 4 times **(See Figure R)**
 - You will feel some increased resistance when you press down
 - You will **not** hear a click when you press down
 - The counter will stay on the red number "8" **(See Figure S)**

Disposal of Bottle and Pouch

1. Put the protective cap back on the spray bottle. Put the empty bottle back into the child-resistant container.
2. Seal the pouch by removing the plastic strip from the flap and folding the flap over (See Figures T and U). Put the sealed pouch into the child-resistant container with the empty bottle.



Figure T



Figure U

3. Place the cap back onto the child-resistant container and twist to close.
4. Throw the child-resistant container with the empty bottle and sealed pouch inside it into the trash.
5. Wash your hands with soap and water.

If you need help with disposal of unused Lazanda bottles, call Archimedes Pharma at 1-866-435-6775 or call your local Drug Enforcement Administration (DEA) office.

If you lose the pouch, use a pouch from another Lazanda pack to prime and dispose of unused medicine from this bottle as well as from the next bottle. If you do not have an empty pouch available, you can order one by calling 1-866-435-6775. You will receive the replacement pouch in the mail.

If you need to continue using Lazanda, open a new bottle and see the Instructions for Use section of this Medication Guide about "Preparing Lazanda for Use."

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

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