**Medication Guide**

**Lazanda® (La-ZAN-da) CII**
(fentanyl) nasal spray

**IMPORTANT:**
Do not use LAZANDA 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 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.

LAZANDA is:
- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage breakthrough pain in adults (18 years of age and older) with cancer 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.
- A nasal spray. You use LAZANDA by placing the nozzle attached to the bottle in your nostril and spraying. See the Medication Guide section “When taking LAZANDA” and the “Instructions for Use” at the end of this Medication Guide.
- 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 LAZANDA:**
- Get emergency help right away if you take too much LAZANDA (overdose). When you first start taking LAZANDA, when your dose is changed, or if you take too much (overdose), serious or life-threatening breathing problems that can lead to death may occur.
- Taking LAZANDA 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 LAZANDA. They could die from taking it. Selling or giving away LAZANDA is against the law.
- Store Lazanda securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.
- If you stop taking your around-the-clock opioid pain medicine for your cancer pain, you must stop using LAZANDA. You may no longer be opioid tolerant. Talk to your healthcare provider about how to treat your pain.
- LAZANDA is available only through a program called the Transmucosal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (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
- 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.

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.

**Do not take LAZANDA 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 LAZANDA. See the end of this Medication Guide for a complete list of ingredients in LAZANDA.
- 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 LAZANDA, 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
- 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 LAZANDA during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
- Breastfeeding. LAZANDA passes into breast milk and may harm your baby.
- Taking prescription over-the-counter medicines, vitamins, or herbal supplements. Taking LAZANDA with certain other medicines can cause serious side effects that could lead to death.

The possible side effects of LAZANDA:

- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain, weakness, anxiety, depression, rash, trouble sleeping, low red blood cell count, swelling of the arms, hands, legs and feet. Call your healthcare provider if you have any of these symptoms and they are severe.
- Decreased blood pressure. This can make you feel dizzy or lightheaded if you get up too fast from sitting or lying down.

Get emergency medical help if you have:

- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue, or throat, extreme drowsiness, light-headedness when changing positions, feeling faint, agitation, high body temperature, trouble walking, stiff muscles, or mental changes such as confusion.
- These symptoms can be a sign that you have used 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 use any more LAZANDA until you have talked to your healthcare provider.

These are not all the possible side effects of LAZANDA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. For more information go to dailymed.nlm.nih.gov

When taking LAZANDA:

- Dispose of expired, unwanted, or unused LAZANDA by the following the “Disposing of LAZANDA” directions in the Instructions for Use. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.
- Know that LAZANDA comes in 3 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.
- See the detailed Patient Instructions for Use at the end of this Medication Guide for information about how to use LAZANDA.

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, 2, 3 or 4 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
  - 3 sprays are given by spraying alternately into each nostril as follows:
    - 1 time right nostril, 1 time left nostril, 1 time right nostril for a total of 3 sprays
  - 4 sprays are given by spraying 2 times into each nostril
    - Change (alternate) nostrils for each spray, for example, right, left, right, left for a total of 4 sprays.

- You must never use more than 4 sprays (2 sprays in alternating nostrils) 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.
- Do not stop taking LAZANDA without talking to your healthcare provider.
- After you stop taking, or when LAZANDA is no longer needed, see “How should I dispose of LAZANDA when it is no longer needed?” for proper disposal of LAZANDA.
- DO NOT Drive or operate heavy machinery, until you know how LAZANDA affects you. LAZANDA 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 LAZANDA may cause you to overdose and die.
- DO NOT Switch from LAZANDA to other medicines that contain fentanyl without talking to 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
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.

Priming 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).

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).

   • 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

8. Wash your hands with soap and water.

Re-priming the bottle:

If you have not used the Lazanda bottle for more than 5 days, re-prime by spraying 1 time into the pouch.

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.

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).

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. If your healthcare provider has prescribed four sprays, repeat steps 4 through 7, but use alternate nostrils (for example, right, left, right, left).

10. 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.

11. Stay sitting down for at least 1 minute after using Lazanda.

12. Avoid blowing your nose for at least 30 minutes after each spray.

13. 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.

**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 60 days or longer since you first used 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.**

- 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.

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 West Therapeutic Development, LLC at 1-844-452-9263 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 1-844-452-9263. 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 U.S. Food and Drug Administration.

West Therapeutic Development, LLC, Northbrook, IL 60062

Revised: February 2020

141010

Lazanda® is a registered trademark licensed to West Therapeutic Development, LLC

©2020 West Therapeutic Development, LLC

All rights reserved.