INDICATIONS AND USAGE
LAZANDA is indicated for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.

IMPORTANT SAFETY INFORMATION
WARNING: LAZANDA CAN CAUSE LIFE-THREATENING BREATHING PROBLEMS THAT CAN LEAD TO DEATH. LAZANDA CAN CAUSE DEATH IN CHILDREN AND OTHERS FOR WHOM IT HAS NOT BEEN PRESCRIBED. LAZANDA MUST BE TAKEN EXACTLY AS PRESCRIBED BY YOUR HEALTHCARE PROVIDER. THE USE OF SOME OTHER MEDICINES CAN CAUSE SERIOUS OR LIFE-THREATENING MEDICAL PROBLEMS WHEN TAKEN WITH LAZANDA. LAZANDA CARRIES A RISK OF ADDICTION, ABUSE AND MISUSE. LAZANDA MAY ONLY BE DISPENSED THROUGH A RESTRICTED PROGRAM CALLED TIRF REMS. USE OF LAZANDA DURING PREGNANCY MAY CAUSE SERIOUS HARM TO YOUR NEWBORN BABY
See full prescribing information for complete boxed warning.
LAZANDA can cause life-threatening breathing problems that can lead to death:
• Do not take LAZANDA if you are not opioid tolerant, or for short-term pain that you would expect to go away in a few days, such as: pain after surgery, headache or migraine, or dental pain. Do not take LAZANDA if you are allergic to fentanyl or any of the ingredients in LAZANDA.
• LAZANDA can cause breathing problems that can become life-threatening. 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) or feel faint, very dizzy, confused, or have other unusual symptoms.
• LAZANDA can cause an overdose and death in any child who takes it. Always keep LAZANDA in a safe place away from children and from anyone for whom it has not been prescribed.
• Do not take any medication while using LAZANDA until you have talked to your healthcare provider. 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.
• The amount of fentanyl in a dose of LAZANDA is not the same as the amount of fentanyl in other medicines that contain fentanyl.
• Do not switch from LAZANDA to other medicines that contain fentanyl without talking with your healthcare provider.
• LAZANDA carries a risk of physical dependence, abuse and addiction. Tell your healthcare provider if you have a past, present or family history of drinking problems (alcoholism), drug abuse or addiction.
• LAZANDA may be dispensed only through a restricted program called the TIRF REMS Access program. To receive LAZANDA you must talk to your health care provider, understand the benefits and risks of LAZANDA, agree to all of the instructions and sign the Patient-Prescriber Agreement form.
• Prolonged use of LAZANDA during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.

Please see full Indications and Usage, full Boxed Warning, and additional Important Safety Information throughout document. Please see enclosed full Prescribing Information, including Medication Guide, for more information about LAZANDA®.
Understanding your breakthrough cancer pain (BTPc)

What is BTPc?
BTPc is an intense pain that can come on without warning. It's called “breakthrough pain” because it occurs even if you're using other opioid medicine to treat cancer pain.²

BTPc can occur at the end of your dose of persistent pain medication, or it can be brought on by something as simple as swallowing or hiccuping.³

How many people get BTPc?
BTPc may be more common than you think. As many as 95% of cancer patients get BTPc, so you're definitely not alone.⁵

Relief from BTPc is possible. Talk to your doctor to develop a pain management treatment plan that meets your needs.

Treating breakthrough pain
• Raising the dose of your current medicine may not prevent the breakthrough pain and can result in overmedication.
• The ideal treatment for BTPc is a short-acting opioid medication that works quickly and lasts about as long as a breakthrough pain episode.⁵

Consequences of breakthrough pain
Without treatment, BTPc flares can harm a person's sense of well-being, interfere with daily activities, interrupt treatment schedules, and even make it more difficult to treat persistent pain.²

What can I do?
Relief from BTPc is possible.
Talk to your doctor to develop a pain management treatment plan that meets your needs.

IMPORTANT SAFETY INFORMATION
Do not use LAZANDA unless you are regularly using another opioid pain medicine around-the-clock for your cancer pain.

Do not use for short-term pain that you would expect to go away in a few days, such as: pain after surgery, headache or migraine, or dental pain.

LAZANDA is only available through a restricted distribution program called the TIRF REMS ACCESS program. To receive LAZANDA, you must:
• talk to your healthcare provider about LAZANDA
• understand the benefits and risks of LAZANDA
• agree to all of the instructions for using LAZANDA
• sign the Patient-Prescriber Agreement form which means that you understand all the risks and benefits of LAZANDA and how to use, safeguard, store, and dispose of LAZANDA

Keep Lazanda in a safe place away from children and from anyone for whom it has not been prescribed.
Reach for relief with LAZANDA®

What is LAZANDA®?

LAZANDA (La-ZAN-da) (fentanyl) nasal spray is a prescription medicine 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.

You should not use LAZANDA unless you are regularly using another opioid medicine around-the-clock and your body is used to these medicines (this means that you are opioid tolerant). You should ask your healthcare provider if you are opioid tolerant. You must continue to take your regular around-the-clock opioid medication while taking LAZANDA.

How do I use LAZANDA®?

Take Lazanda exactly as prescribed by your healthcare provider.

ALL patients start with one 100 mcg dose in one nostril. Talk to your healthcare provider if your dose of Lazanda does not relieve your breakthrough cancer pain. Always follow his or her instructions.

Do not change your dose of Lazanda unless your healthcare provider tells you to.

Your healthcare provider will determine the lowest effective dosage for your pain.

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.

IMPORTANT SAFETY INFORMATION

Get emergency 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® can work to reduce breakthrough pain intensity within 30 minutes:

• Pain was reduced for some patients in as early as 5 minutes
• Pain relief lasted for at least an hour

Are there any dietary restrictions?

Since LAZANDA® is a nasal spray and not an oral medicine, you may eat or drink before or after you take LAZANDA®. Note that you must not drink alcohol when taking LAZANDA®, as this may lead to dangerous side effects. Do not drink grapefruit juice while taking LAZANDA®.

What are some of the most commonly reported side effects?

Side effects include:

• vomiting
• nausea
• constipation
• dizziness
• fever

For a complete list of side effects, talk with your healthcare provider, and read the Medication Guide that accompanies this booklet.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.
IMPORTANT SAFETY INFORMATION

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, have been taking them for at least one week, and your body is used to these medicines.
- you have short-term pain that you would expect to go away in a few days, such as: pain after surgery, headache or migraine, or dental pain.
- 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 fentanyl or any of the ingredients in Lazanda.

WARNINGS AND PRECAUTIONS

Life-Threatening Breathing Problems
Lazanda can cause serious breathing problems that can be life-threatening and if it is not treated, can cause death. The risk is highest when you are being started on LAZANDA and when your dose is being increased. It is essential to follow the proper instructions for dosing and dose increase. If you overestimate the dose, it can cause a fatal overdose. Lazanda can cause death if it is taken by someone for whom it has not been prescribed or if it is taken by someone who is not opioid tolerant. Accidentally taking or being exposed to even one dose of Lazanda, especially by children, can cause life-threatening breathing problems and a fatal overdose.

High Risk of Overdose in Children
Death has occurred in children who accidentally took drugs containing fentanyl. You and your caregiver must know that LAZANDA contains fentanyl in an amount which can cause death in children. Always keep Lazanda in a safe place away from children and anyone for whom it has not been prescribed.

Risk of Using or Discontinuing Certain Medications While Taking LAZANDA

Using or discontinuing certain medicines while taking LAZANDA may cause fatal respiratory depression. Do not take any other 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. Tell your healthcare provider about all the medicines you take, including prescription and nonprescription medicines, vitamins and herbal supplements. Sometimes, the doses of certain medicines and Lazanda need to be changed if used together.

Risk of Medication Errors

The amount of fentanyl delivered by a dose of Lazanda is not the same as in other medicines that contain fentanyl. DO NOT substitute any other fentanyl product instead of LAZANDA and DO NOT switch to any other fentanyl product in place of LAZANDA. Substitution of LAZANDA for any other fentanyl product can cause a fatal overdose. Your healthcare provider will start you on ONE 100 mcg spray.

Risk of Abuse or Addiction

Lazanda contains fentanyl which is a Schedule II controlled substance. LAZANDA carries the risk of abuse, addiction and misuse. 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 illness. Tell your healthcare provider if you have a past or present drinking problem (alcoholism), or a family history of drinking problems. Tell your healthcare provider if you have a past or present problem with drug abuse or addiction, or a family history of drug abuse or addiction. Tell your healthcare provider if you have mental health problems such as depression, hallucinations or confusion.

Transmucosal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS) Access Program

Because of the risk of misuse, abuse, addiction and overdose, Lazanda is only available through 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 and sign the Patient-Prescriber Agreement form.

Risk to Your Newborn Baby

Prolonged use of Lazanda during pregnancy can cause withdrawal effects in your newborn baby that could be life-threatening if not recognized and treated. Tell your healthcare provider if you are pregnant or planning to become pregnant.

Risk of Life-Threatening Breathing Problems in Patients with Asthma or Lung Problems or in Weakened Condition

Lazanda can cause life-threatening breathing problems. Tell your healthcare provider if you have breathing or lung problems such as asthma, wheezing, shortness of breath or any other lung (pulmonary, respiratory) problems.

Risk of Serious or Life-Threatening Medical Problems if Taken with Medicines that Treat Psychiatric Disorders Like Depression

Some medicines may cause serious or life-threatening medical problems when taken with Lazanda. Do not take any other 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 like anti-depressants, anti-anxiety medicines or tranquilizers. Tell your healthcare provider about all the medicines you take.
How to take LAZANDA®

Steps to help you remember

Below is a summary of how to take LAZANDA®.

SETTING UP

Priming the bottle

- Remove the protective cap from the nozzle (tip)
- Place the tip of the LAZANDA® bottle into the opening of the pouch. Hold the LAZANDA® bottle so that the spray goes into the pouch

The counting window

- A new bottle will show 2 thin red lines in the counting window
- Firmly press on the grips until you hear a click, and you will see one red bar in the counting window
- Keep pressing and releasing 3 more times (for a total of 4 times). Each time the red bar will become smaller

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (Continued)

Adrenal Insufficiency

Lazanda poses a risk of problems related to the adrenal glands which produce a variety of hormones that your body needs.

Risk of Severe Decreased Blood Pressure

Lazanda can cause or increase severe low blood pressure that can make you feel dizzy or lightheaded if you get up too fast from sitting or lying down. Tell your doctor if you have low blood pressure.

Risk to Patients with a Head Injury or Brain Problem

Lazanda poses risk to patients who have or have had a head injury or brain problem. Tell your healthcare provider if you have or have had a head injury, a brain tumor or other brain problems.

For complete instructions, including LAZANDA® preparation, storage, and disposal, consult the Medication Guide in the pocket of this booklet, and visit www.LAZANDA.com/how_to_use for a video demonstration.

PREPARING TO TAKE LAZANDA®

Getting started

- You should see a green bar or a number in the dose-counting window
  — This tells you LAZANDA® is ready to use

Remove bottle tip

- Remove the protective cap
- Hold the bottle between your thumb and fingers

ADMINISTERING YOUR LAZANDA® DOSE

Insert bottle tip

- If you have a runny nose, blow your nose now
- Insert the bottle tip into 1 nostril about half an inch
- Tilt the bottle toward the bridge of your nose
- Close off your other nostril with 1 finger

Press. Hear a click

- Press down on the bottle finger grips until you HEAR a CLICK
  — This tells you a full spray has been released from the bottle
- Wash your hands with soap and water

If your healthcare provider has prescribed a second spray, repeat the steps above, spraying into the other nostril.

Please see additional Important Safety Information throughout document.
Please see enclosed full Prescribing Information, including Medication Guide, for more information about LAZANDA®.
After you’ve taken your LAZANDA® dose

LAZANDA® lets you know you’ve taken your dose

ADMINISTERING YOUR LAZANDA® DOSE

Breathe in

- Breathe in gently through your nose and out through your mouth once after spraying
- Do not sniff after spraying the medicine into your nose
- Unlike traditional nasal sprays, you may not feel the spray go into your nose because it is a fine mist. This is normal
- Avoid blowing your nose for at least 30 minutes after each spray

KEEPING TRACK OF YOUR LAZANDA® DOSE

Confirm spray was released

- After each spray, you should see the number in the counting window increase by 1
  - This tells you that medicine has been administered
- Once you see a red number “8” in the counting window, the bottle is finished and there is no longer enough medicine for a full dose.
  Do not try to take another dose of LAZANDA® from this bottle

Important dosing instructions to follow

ALL patients start with one 100 mcg dose in one nostril.

If you are not getting relief, your healthcare provider may adjust your dose. Always follow his or her instructions.

- As your dose is adjusted, your healthcare provider will tell you whether your dose of LAZANDA® is 1, 2, 3, or 4 sprays
- Do not change your dose of LAZANDA® unless your healthcare provider tells you to

9 in 10 patients were satisfied or very satisfied with the ease of use and convenience of LAZANDA® in a clinical study.∗

Always follow your healthcare provider’s instructions.
You must wait 2 hours before treating a new episode of BTPc. ⁶

Please see accompanying Medication Guide for complete instructions on using LAZANDA®.

*Study description: a multicenter, open-label extension study assessing the safety and tolerability of LAZANDA® in 356 patients on background opioids who were experiencing 1 to 4 daily episodes of moderate to severe BTPc.⁴
IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (Continued)

Risk to Patients with Bowel or Stomach Problems
Lazanda poses a risk to patients with a bowel blockage or narrowing of the stomach or intestines.

Tell your doctor if you have any stomach or bowel problems.

Risk of Seizures in Patients with Seizure Disorders
Lazanda may increase the incidence of seizures in patients with seizure disorders. Tell your healthcare provider if you have a history of seizures.

Risks of Driving and Operating Machinery
Do not drive, operate heavy machinery or do other dangerous activities if you feel sleepy or dizzy while taking Lazanda. Ask your healthcare provider when it is okay to do these activities.

Risk to Patients with a Slow Heart Rate or other Heart Problems
Tell your healthcare provider if you have a slow heart rate or other heart problems.

POSSIBLE SIDE EFFECTS OF LAZANDA:
The most common side effects of Lazanda seen in clinical studies are:

• vomiting
• nausea
• constipation
• dizziness
• 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.

Call your healthcare provider or get emergency help right away if you:

Have trouble breathing, shortness of breath with minimal exertion or at rest, 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, hallucinations, or extreme sleepiness.

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.

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.

• You are breastfeeding. Lazanda passes into breast milk and could harm your baby. Do not use Lazanda while breastfeeding.

• You are 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.

These are not all the possible side effects of Lazanda. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

For more information, ask your doctor or pharmacist; or visit www.Lazanda.com for the Medication Guide and the complete full Prescribing Information for Lazanda, which includes a boxed warning.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch; or call 1-800-FDA-1088.

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
• mental problems [including major depression, confusion or hallucinations (seeing or hearing things that are not there)]
• liver, kidney or thyroid problems
• pancreas or gallbladder problems

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Tell your healthcare provider if:

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• You are breastfeeding. Lazanda passes into breast milk and could harm your baby. Do not use Lazanda while breastfeeding.

• You are 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.

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• pancreas or gallbladder problems

Tell your healthcare provider if:

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• You are breastfeeding. Lazanda passes into breast milk and could harm your baby. Do not use Lazanda while breastfeeding.

• You are 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.
FAQs

Why do I need to take another pain medication?
Your current opioid pain medication may be unable to control the intense periods of pain you are feeling. This pain is said to sneak past or “break through” your around-the-clock medication—that is why it is called breakthrough cancer pain (BTPc). LAZANDA® is used to help relieve your BTPc.

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). If you stop taking your around-the-clock opioid pain medicine for your cancer, you must stop taking LAZANDA®.

What is the TIRF REMS ACCESS program?
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

How many sprays of LAZANDA® do I take?
Always follow your healthcare provider’s instructions.

Is there a risk of addiction to LAZANDA®?
Addiction is the inability to control the urge to take medication. Using LAZANDA® can result in addiction, and the chance of addiction is higher if you are or ever have been addicted to or abused other medicines, street drugs, or alcohol, or if you have a history of mental problems.

How can I prevent someone else from taking LAZANDA®?
Keep LAZANDA® in a safe place to protect it from being stolen and out of the reach of children and pets. Store LAZANDA® in the child-resistant container that comes with it at all times except when you are using it.

Talk with your healthcare provider about any other questions you have during treatment.

IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS (Continued)

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 that contain 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 in other medicines that contain fentanyl. Your healthcare provider will prescribe a starting dose of Lazanda that may be different than other fentanyl containing medicines you may have been taking.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.
References:


IMPORTANT SAFETY INFORMATION

LAZANDA is indicated for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.

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