

LAZANDA® (fentanyl) Nasal Spray CII
LAZANDA® Support Program
Frequently Asked Questions (FAQs)

For Additional Information

Call (844) 295-0550

Question	Response
What are the eligibility rules for the LAZANDA® Support Program?	Commercially Insured patients are eligible to Pay \$25 and receive up to \$4,000 on your copay on each prescription for LAZANDA® (fentanyl) Nasal Spray CII. Please present the savings card to your pharmacist along with your valid LAZANDA prescription. Diagnosis information may be required to verify that LAZANDA was prescribed for an FDA-approved use. Any remaining out of pocket costs will be the patient’s responsibility. Maximum benefit under the LAZANDA Support Program is 30 bottles per 30 days. The program is not available to uninsured or cash-paying individuals. Patients who move from commercial to state or federally funded insurance will no longer be eligible for the program. Offer not valid for patients eligible for benefits under Medicaid (including Medicaid managed care), Medicare, TRICARE, Veterans Affairs, or similar state or federal programs. Offer void where prohibited, taxed, or otherwise restricted. Limit one enrollment per individual. Void if card is copied, transferred, purchased, altered, or traded. West Therapeutic Development, LLC., reserves the right to rescind, revoke or amend this program without notice. Please visit www.LAZANDA.com for eligibility details.
How do I use the LAZANDA Savings Card?	Take your LAZANDA Savings Card, along with your valid prescription for LAZANDA to your local pharmacy to receive the benefit.
I did not receive a LAZANDA Savings Card, how can I get one?	Please visit www.LAZANDA.com to print a LAZANDA Savings Card or you may be able to get one from your physician’s office.
How many times can I use my LAZANDA Savings Card?	This card can be used with each LAZANDA prescription and future refills. Benefit is limited to 30 bottles per 30 days.
When does the LAZANDA Savings Card expire?	The card does not have an expiration date. However, West Therapeutic Development, LLC., has the right to rescind, revoke or amend the LAZANDA Savings Card offer at any time.
I’ve previously used my LAZANDA Savings Card and I am not sure how many uses I have left.	The card can be used with each LAZANDA prescription and future refills and the card has no expiration date. Benefit is limited to 30 bottles per 30 days. However, West Therapeutic Development, LLC., has the Right to rescind, revoke or amend the LAZANDA Savings Card offer at any time.

Please see Important Risk Information for LAZANDA, including BOXED WARNING, on pages 3–7.

<p>I'm already taking LAZANDA® (fentanyl) Nasal Spray CII, am I able to use the LAZANDA Savings Card?</p>	<p>Yes. All Commercially Insured patients, new and existing, can use the LAZANDA Savings Card. Please visit www.LAZANDA.com for eligibility requirements and to download a card or see your physician to obtain one.</p>
<p>I'm on Medicare/Medicaid. Can I use the LAZANDA Savings Card?</p>	<p>No. The offer is only valid for patients who have commercial private health insurance, only. Offer not valid for patients who are not insured, cash-paying or have Medicaid, Medicare, TRICARE, and Veterans Affairs or any other state or federal healthcare program (including state prescription drug programs). Offer good only in US and its territories and void where prohibited by law, taxed or restricted. Please visit www.LAZANDA.com for eligibility requirements</p>
<p>What if I get my prescriptions filled through a mail order/specialty pharmacy?</p>	<p>Please call your mail order or specialty pharmacy to confirm that they will accept the LAZANDA Savings Card. If they do not accept the LAZANDA Savings Card, you must pay for your prescription and you can download a form at www.LAZANDA.com and send the prescription receipt along with the form to be reimbursed. Be sure to save your mail order pharmacy receipt for the rebate. We can also email you a manual rebate form by contacting (844) 295-0550. Follow the instructions on the rebate form.</p>
<p>Who do I call to report an adverse event or have any product questions about LAZANDA?</p>	<p>You can contact LAZANDA Adverse/Product Help Line at 1-866-458-6389.</p>

Please see Important Risk Information for LAZANDA, including BOXED WARNING, on pages 3–7.

LAZANDA[®] (Fentanyl) Nasal Spray CII

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.

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.

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.

Please see Important Risk Information for LAZANDA, including BOXED WARNING, on pages 3–7.

IMPORTANT SAFETY INFORMATION (CONTINUED)

To receive LAZANDA (fentanyl) nasal spray CII, 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.

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.

HOW TO TAKE 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.

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

Please see Important Risk Information for LAZANDA, including BOXED WARNING, on pages 3–7.

IMPORTANT SAFETY INFORMATION (CONTINUED)

take other medicines while you are using LAZANDA (fentanyl) nasal spray CII. 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.**

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.

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.

Please see Important Risk Information for LAZANDA, including BOXED WARNING, on pages 3–7.

IMPORTANT SAFETY INFORMATION (CONTINUED)

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 (fentanyl) nasal spray CII. 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.

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 health care 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

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.

Please see Important Risk Information for LAZANDA, including BOXED WARNING, on pages 3–7.

IMPORTANT SAFETY INFORMATION (CONTINUED)

DO NOT Drive or operate heavy machinery until you know how LAZANDA (fentanyl) nasal spray CII 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.

Please [click here](#) for Lazanda full Prescribing Information, including **BOXED WARNING**, and Medication Guide.

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