

MEDICATION GUIDE
NAYZILAM® (NAY-zil-am)
(midazolam) nasal spray, CIV

What is the most important information I should know about NAYZILAM?

- **NAYZILAM is a benzodiazepine medicine. Taking benzodiazepines with opioid medicines, alcohol, or other central nervous system (CNS) depressants (including street drugs) can cause severe drowsiness, breathing problems (respiratory depression), coma, and death.**
- Get emergency medical help right away if any of the following happens:
 - shallow or slowed breathing
 - breathing stops (which may lead to the heart stopping)
 - excessive sleepiness (sedation)Do not drive or operate heavy machinery until you know how taking NAYZILAM with opioids may affect you.
- **Risk of abuse, misuse, and addiction.** There is a risk of abuse, misuse, and addiction with benzodiazepines, including NAYZILAM, which can lead to overdose and serious side effects including coma and death.
 - **Serious side effects including coma and death have happened in people who have abused or misused benzodiazepines, including midazolam (the active ingredient in NAYZILAM).** These serious side effects may also include delirium, paranoia, suicidal thoughts or actions, seizures, and difficulty breathing. **Call your healthcare provider or go to the nearest hospital emergency room right away if you have any of these serious side effects.**
 - **You can develop an addiction even if you use NAYZILAM as prescribed by your healthcare provider.**
 - **Use NAYZILAM exactly as your healthcare provider prescribed.**
 - **Do not share your NAYZILAM with other people.**
 - **Keep NAYZILAM in a safe place and away from children.**
- **Physical dependence and withdrawal reactions.** Benzodiazepines, including NAYZILAM, can cause physical dependence and withdrawal reactions, especially if you use NAYZILAM daily. NAYZILAM is not intended for daily use.
 - **Do not suddenly stop using NAYZILAM without talking to your healthcare provider.** Stopping NAYZILAM suddenly can cause serious and life-threatening side effects, including, unusual movements, responses, or expressions, seizures, sudden and severe mental or nervous system changes, depression, seeing or hearing things that others do not see or hear, an extreme increase in activity or talking, losing touch with reality, and suicidal thoughts or actions. **Call your healthcare provider or go to the nearest hospital emergency room right away if you have any of these symptoms.**
 - **Some people who suddenly stop benzodiazepines have symptoms that can last for several weeks to more than 12 months,** including, anxiety, trouble remembering, learning, or concentrating, depression, problems sleeping, feeling like insects are crawling under your skin, weakness, shaking, muscle twitching, burning or prickling feeling in your hands, arms, legs or feet, and ringing in your ears.
 - Physical dependence is not the same as drug addiction. Your healthcare provider can tell you more about the differences between physical dependence and drug addiction.
 - **Do not use more NAYZILAM than prescribed or use NAYZILAM more often than prescribed.**
- **NAYZILAM can make you sleepy or dizzy and can slow your thinking and motor skills.**
 - Do not drive, operate heavy machinery, or do other dangerous activities until you know how NAYZILAM affects you.
 - Do not drink alcohol or take other drugs that may make you sleepy or dizzy while using NAYZILAM without first talking to your healthcare provider. When taken with alcohol or drugs that cause sleepiness or dizziness, NAYZILAM may make your sleepiness or dizziness worse.
- **Like other antiepileptic medicines, NAYZILAM may cause suicidal thoughts or actions in a very small number of people, about 1 in 500. Call your healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you:**
 - thoughts about suicide or dying
 - trouble sleeping (insomnia)

- feeling agitated or restless
- acting aggressive, being angry, or violent
- attempts to commit suicide
- panic attacks
- acting on dangerous impulses
- new or worse depression
- an extreme increase in activity and talking (mania)
- new or worse anxiety
- new or worse irritability
- other unusual changes in behavior or mood

How can I watch for early symptoms of suicidal thoughts or actions?

- Pay attention to any changes, especially sudden changes in mood, behaviors, thoughts, or feelings.
 - Keep all follow-up visits with your healthcare provider as scheduled.
- Call your healthcare provider between visits as needed, especially if you are worried about symptoms. Suicidal thoughts or actions can be caused by things other than medicines. If you have suicidal thoughts or actions, your healthcare provider may check for other causes.

What is NAYZILAM?

- NAYZILAM is a prescription medicine used for the short-term treatment of seizure clusters (also known as “acute repetitive seizures”) in people 12 years of age and older.
- **NAYZILAM is a federally controlled substance (CIV) because it contains midazolam that can be abused or lead to dependence.** Keep NAYZILAM in a safe place to prevent misuse and abuse. Selling or giving away NAYZILAM may harm others and is against the law. Tell your healthcare provider if you have ever abused or been dependent on alcohol, prescription drugs, or street drugs.
- It is not known if NAYZILAM is safe and effective in children under 12 years of age.

Do not use NAYZILAM if you:

- are allergic to midazolam.
- have an eye problem called acute narrow-angle glaucoma.

Before you use NAYZILAM, tell your healthcare provider about all your medical conditions, including if you:

- have a history of depression, mood problems or suicidal thoughts or behavior.
- have asthma, emphysema, bronchitis, chronic obstructive pulmonary disease, or other breathing problems.
- have kidney or liver problems.
- have congestive heart failure.
- have a history of drug or alcohol abuse.
- are pregnant or plan to become pregnant. NAYZILAM may harm your unborn baby.
 - Babies born to mothers receiving benzodiazepine medicines (including NAYZILAM) late in pregnancy may be at risk of having breathing problems, feeding problems, dangerously low body temperature, and withdrawal symptoms.
 - If you become pregnant while using NAYZILAM, talk to your healthcare provider about registering with the North American Antiepileptic Drug (NAAED) Pregnancy Registry. You can register by calling 1-888-233-2334. For more information about the registry, go to <http://www.aedpregnancyregistry.org>. The purpose of this registry is to collect information about the safety of antiepileptic drugs during pregnancy.
- are breastfeeding or plan to breastfeed. Midazolam passes into your breast milk and may harm your baby. Talk to your healthcare provider about the best way to feed your baby if you use NAYZILAM.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. Using NAYZILAM with certain other medicines can affect each other, causing side effects. Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist each time you get a new medicine. Ask your healthcare provider or pharmacist for a list of these medicines if you are not sure.

How should I use NAYZILAM?

- Use NAYZILAM in the nose only.
- **Use NAYZILAM exactly as your healthcare provider tells you to use it** and follow the Instructions for Use that comes with this Medication Guide.
- Your healthcare provider has prescribed NAYZILAM to treat a type of seizure called a “seizure cluster”.
- If the seizure cluster is continuing **10 minutes** after the first dose of NAYZILAM, a second dose of NAYZILAM may be used if you have been told to do so by your healthcare provider.

- If a second dose of NAYZILAM is used, give the second dose in the other nostril.
- **Do not** give more than 2 doses of NAYZILAM to treat a seizure cluster.
- **If the seizures do not stop** after NAYZILAM is used, get emergency medical help right away.
- **Do not** use NAYZILAM for more than 1 seizure cluster episode every 3 days. **Do not** use NAYZILAM for more than 5 seizure cluster episodes per month.
- If benzodiazepines are stopped after a person takes them daily, they can cause withdrawal symptoms. Stopping benzodiazepines suddenly can cause seizures that will not stop (status epilepticus), hearing or seeing things that are not there (hallucinations), shaking, nervousness, and stomach and muscle cramps. NAYZILAM is not intended to be used daily.
- If you use too much NAYZILAM, call your healthcare provider or go to the nearest emergency room right away.

What should I avoid while using NAYZILAM?

See “What is the most important information I should know about NAYZILAM?”

What are the possible side effects of NAYZILAM?

NAYZILAM may cause serious side effects, including:

- See “What is the most important information I should know about NAYZILAM?”
- **Increase in eye pressure in people with acute narrow-angle glaucoma.** See “Do not use NAYZILAM if you:”

The most common side effects of NAYZILAM include:

- | | |
|--------------|---------------------|
| • sleepiness | • nasal discomfort |
| • headache | • throat irritation |
| • runny nose | |

These are not all the possible side effects of NAYZILAM. 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 NAYZILAM?

- Store NAYZILAM at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep NAYZILAM in the blister package until ready to use.

Keep NAYZILAM and all medicines out of the reach of children.

General information about the safe and effective use of NAYZILAM.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use NAYZILAM for a condition for which it was not prescribed. Do not give NAYZILAM to other people, even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about NAYZILAM that is written for health professionals.

What are the ingredients in NAYZILAM?

Active ingredient: midazolam

Inactive ingredients: ethanol, PEG-6 methyl ether, polyethylene glycol 400, propylene glycol and purified water

Manufactured for UCB, Inc., Smyrna, GA 30080.

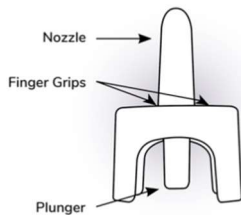
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For more information, go to www.nayzilam.com or call 1-844-599-2273.

Instructions for Use
NAYZILAM® (NAY-zil-am)
(midazolam) nasal spray, CIV

You and your family members or caregivers should read this Instructions for Use before you start using NAYZILAM nasal spray and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment. If you and your family members or caregivers have any questions about NAYZILAM, ask your healthcare provider or pharmacist.



Important: NAYZILAM is for use in the nose only.

- **There is only 1 dose of NAYZILAM in the nasal spray unit.**
- **Do not** try to test or prime the nasal spray unit before use. You will lose the dose.
- **Do not** open the blister packaging until ready to use.
- **Do not** use if the nasal spray unit appears damaged.
- **Do not** use past the expiration date printed on the blister packaging.
- Throw away (dispose of) the nasal spray unit after use.

How to use NAYZILAM nasal spray:

Step 1: Peel open the blister packaging

- When ready to use, open the blister packaging.
- Hold blister packaging in the palm of your hand.
- On the foil backing, find the “**Peel Here**” tab and pull down (**see Figure 1**).
- Remove the nasal spray unit carefully.

Figure 1



Figure 2



Step 2: Hold the nasal spray unit

- Hold the nasal spray unit with your thumb on the plunger and your middle and index fingers on each side of the nozzle (**see Figure 2**).
- **Do not press the plunger yet. If you press the plunger now, you will lose the dose.**

Figure 3



Figure 4



Step 3: Place the tip into 1 nostril

- Place the tip of the nozzle into 1 nostril until your fingers on either side of the nozzle touches the bottom of the nose (**see Figure 3**).

Step 4: Press the plunger

- Press the plunger firmly to deliver the dose of NAYZILAM nasal spray (**see Figure 4**).
- Make sure to firmly press the plunger using 1 motion.

The patient does not need to breathe deeply when you give them the medicine.

What to do after the NAYZILAM nasal spray has been used:

Remove the nozzle from the nostril after giving the dose.

Note: The plunger will remain inside the nasal spray unit after the dose is given.

Throw away (dispose of) the nasal spray unit and blister packaging in the trash.

What to do if a Second Dose is needed:

Important: If the seizure cluster is continuing **10 minutes** after the first dose of NAYZILAM, a second dose of NAYZILAM **may be used if you have been told to do so by your healthcare provider.**

If you need to give a second dose of NAYZILAM, follow the instructions in this Instructions for Use using a new nasal spray unit **in the other nostril.** (Repeat Step 1 through Step 4)



Call for help if any of the following happens:

- Seizure or seizures continue after giving NAYZILAM to the person as instructed by the healthcare provider.
- Seizure behavior in the person is different from other episodes.

Local Emergency Number:

Healthcare Provider's Number:

- You are alarmed by the number or severity of the seizure or seizures in the person.
- You are alarmed by the color or breathing of the person.

Information for Emergency Responder

Time of first NAYZILAM
dose: _____

Time of second NAYZILAM dose (if
given): _____

Manufactured for UCB, Inc., Smyrna, GA 30080.

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For more information, go to www.nayzilam.com or call 1-844-599-2273.

This Instructions for Use has been approved by the U.S. Food and Drug Administration

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