

NAYZILAM is a prescription medicine used for the short-term treatment of seizure clusters (also known as "acute repetitive seizures") in patients 12 years of age and older.

#### IMPORTANT SAFETY INFORMATION

NAYZILAM is a benzodiazepine medicine. Taking benzodiazepines with opioid medicines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, breathing problems (respiratory depression), coma, and death. 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. Benzodiazepines, including NAYZILAM, can cause physical dependence and withdrawal reactions, especially if you continue to use NAYZILAM daily. NAYZILAM (midazolam) nasal spray

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Please see additional Important Safety Information on pages 15-19 and the enclosed Patient Medication Guide in this brochure's pocket.

Visit www.NAYZILAM.com to learn more about treatment with NAYZILAM.

# GETTING STARTED WITH NAYZILAM

Your healthcare provider has prescribed NAYZILAM\* (midazolam) nasal spray, CIV as a way to help you or a loved one manage seizure clusters when they happen.

This guide will help you to understand:

- · What seizure clusters are
- How to manage them
- How NAYZILAM can help treat them quickly

Living with seizure clusters can be worrisome, but now you can have the peace of mind that comes from having a fast-acting rescue medication in a ready-to-use nasal spray.



PLEASE TALK TO YOUR HEALTHCARE PROVIDER IF YOU HAVE ANY QUESTIONS OR CONCERNS ABOUT NAYZILAM. "My best friend, Merna, has been in so many situations where I've had seizure clusters, and she knows exactly what to do. Having NAYZILAM with me, and knowing that she's able to use it, would be so helpful whether we're out together or just hanging out."

- Eva W., seizure cluster patient

#### **IMPORTANT SAFETY INFORMATION**

NAYZILAM may cause serious side effects, including: interaction with other central nervous system depressants, serious breathing problems and excessive sleepiness, risk of abuse, misuse, and addiction, physical dependence with withdrawal reactions, suicidal thoughts or actions, impaired mental alertness including memory problems, increase in eye pressure in people with acute narrow-angle glaucoma, and may cause your baby to have symptoms of sedation (breathing problems, sluggishness, low muscle tone), and/or withdrawal symptoms (jitteriness, irritability, restlessness, shaking, excessive crying, feeding problems). Breastfeeding during treatment with NAYZILAM may cause your baby to have sleepiness, feeding problems, and decreased weight gain. The most common side effects of NAYZILAM include sleepiness, nasal discomfort, headache, throat irritation and runny nose.



# UNDERSTANDING SEIZURE CLUSTERS

Seizure clusters are disruptive events that can leave you feeling worried, frustrated, or helpless.



#### WHAT ARE SEIZURE CLUSTERS?

Seizure clusters are periods of increased seizure activity, which is having two or more seizures in a 24-hour period.

You may experience seizures, but *seizure clusters* are different from your usual seizure pattern. This can mean having several seizures in a row or they can be hours apart. Seizure clusters can be different from one person to the next, in terms of number of seizures in a cluster, type of seizure, severity, or how long they last. Your healthcare provider can help you to identify seizure clusters, and when and how to use a rescue medication to treat them.

You may have heard of seizure clusters, or your healthcare provider may call them something else, such as:

- · Acute repetitive seizures
- Serial seizures
- Recurrent seizures

- Multiple seizures
- Crescendo seizures
- Seizure flurries

SEIZURE = 2 OR MORE SEIZURES IN 24 HOURS

## WHY IT'S URGENT TO TREAT SEIZURE CLUSTERS

Seizure clusters may happen without warning and can lead to serious health consequences, such as:

- · Injuries
- Hospitalization
- Longer seizures or more dangerous activity, called status epilepticus, which is a seizure lasting longer than five minutes

That's why it's important to have a rescue medication on hand during a seizure cluster emergency, and to use it as soon as possible.

What matters most is having the reassurance of a rescue treatment that:

- · Works fast to stop a seizure cluster
- · Allows you to feel like yourself again
- · Prevents additional seizures within the cluster
- · Can be given by anyone, anywhere

A rescue medication is different from the daily epilepsy medications you already take to manage your epilepsy. Keep taking your daily seizure medication as directed by your healthcare provider, and use your prescribed rescue medication when you need it to treat a seizure cluster.





## WHAT IS NAYZILAM?

NAYZILAM® (midazolam) nasal spray, CIV is a prescription medicine used for the short-term treatment of seizure clusters (also known as acute repetitive seizures) in patients 12 years of age and older. It is a rescue medication in the form of a nasal spray.

Do not use NAYZILAM if you have an eye problem called acute narrow-angle glaucoma.

You don't have to wait to treat a seizure cluster with NAYZILAM. This nasal spray can be given during or immediately after the first seizure if a cluster occurs, even if the person is unconscious—no inhaling is necessary.

Prior to using NAYZILAM, the person giving it should know how to identify seizure clusters and how to use this rescue medication appropriately.



Midazolam, the active ingredient in NAYZILAM, belongs to a class of medications called benzodiazepines [ben-zoh-dahy-az-uh-peens]. Benzodiazepines, sometimes called "benzos," have been an important treatment option for epilepsy for decades. They are central nervous system depressants and have an anticonvulsant effect thought to occur by making the nerves in the brain less sensitive to stimulation.



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Visit www.NAYZILAM.com to learn more about treatment with NAYZILAM.



NAYZILAM is different from daily epilepsy medications prescribed to manage epilepsy. Keep taking your daily seizure medication as directed by your healthcare provider, and use NAYZILAM when you need to treat a seizure cluster.

To learn more about NAYZILAM, please visit www.NAYZILAM.com.

#### IMPORTANT SAFETY INFORMATION

NAYZILAM is a benzodiazepine medicine. Taking benzodiazepines with opioid medicines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, breathing problems (respiratory depression), coma, and death. 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. Benzodiazepines, including NAYZILAM, can cause physical dependence and withdrawal reactions, especially if you continue to use NAYZILAM daily. NAYZILAM is not intended for daily use.

## **HOW NAYZILAM CAN HELP**

Now you have the reassurance of NAYZILAM® (midazolam) nasal spray, CIV within reach to help manage seizure clusters quickly and get back to your day.

IN A STUDY, NAYZILAM HELPED THE MAJORITY OF PATIENTS TO STOP A SEIZURE CLUSTER FAST AND RETURN TO FUNCTION WITHIN 90 MINUTES.

NAYZILAM may cause serious side effects, including impaired mental alertness including memory problems.

The most common side effects reported with NAYZILAM use include:

- Sleepiness
- · Throat irritation
- Headache
- Runny nose
- Nasal discomfort

These are not all the possible side effects of NAYZILAM. Call your healthcare provider for medical advice about side effects.



STOP SEIZURE CLUSTERS SO THEY DON'T STOP YOU. WITH NAYZILAM WITHIN REACH, NOW YOU CAN BE READY TO TREAT THEM QUICKLY.



Please see additional Important Safety Information on pages 15-19 and the enclosed Patient Medication Guide in this brochure's pocket.

Visit www.NAYZILAM.com to learn more about treatment with NAYZILAM.

**NAYZILAM MAY HELP YOU TO:** 

STOP SEIZURE CLUSTERS
WITHIN MINUTES
Prevent further seizure

Prevent further seizure activity for up to 6 hours

GET BACK TO FEELING LIKE YOURSELF WITHIN HOURS

KEEP MORE SEIZURES FROM RETURNING FOR 24 HOURS



## **USING NAYZILAM**



#### FIRST DOSE:

Use one 5 mg nasal spray in one nostril.



#### SECOND DOSE (if needed):

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

If a second dose is used, give the second dose in the other nostril.



DO NOT GIVE MORE THAN 2 DOSES TO TREAT A SEIZURE CLUSTER



Nayzilam®



EACH BOX CONTAINS TWO SINGLE-USE NASAL SPRAY DEVICES



STORE AT ROOM TEMPERATURE

Navzilam®@

#### **ABOUT USING NAYZILAM**

It's important to know a few things before you or someone else administers NAYZILAM® (midazolam) nasal spray, CIV, so everyone can feel more comfortable using it.

- NAYZILAM is not intended to be used daily. Use exactly as your healthcare provider tells you to use it (in the nose, never more than two doses). If you use too much of this medication, call your healthcare provider or go to the nearest emergency room right away.
- If the seizures do not stop after the nasal spray is used, get emergency medical help right away.
- Do not use this medication for more than 1 seizure cluster episode every 3 days and no more than 5 seizure cluster episodes per month.

Please see the enclosed Medication Guide for more information.



Please see additional Important Safety Information on pages 15-19 and the enclosed Patient Medication Guide in this brochure's pocket.

Visit www.NAYZILAM.com to learn more about treatment with NAYZILAM.



## **HOW TO GIVE NAYZILAM**

NAYZILAM® (midazolam) nasal spray, CIV is a ready-to-use nasal spray that can be given by anyone, whenever seizure clusters occur.

The complete steps on how to use NAYZILAM are found in the Instructions for Use in the pocket of this brochure. An overview of the steps is below.



AFTER PEELING OPEN THE BLISTER PACK, FOLLOW THESE STEPS.

### HOLD

Hold the nasal spray device with your thumb on the plunger and your middle and index fingers on each side of the nozzle.



DO NOT PRESS THE PLUNGER YET.

### **PLACE**

Place the tip of the nozzle into one nostril until your fingers are against the bottom of the patient's nose.



### PRESS

Press the plunger firmly.





REMEMBER TO THROW AWAY (DISPOSE OF) THE NASAL SPRAY DEVICE AND BLISTER PACKAGING.

NOW YOU CAN FEEL READY TO TREAT SEIZURE CLUSTERS ANYTIME WITH NAYZILAM.



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Visit www.NAYZILAM.com to learn more about treatment with NAYZILAM.

## IMPORTANT SAFETY INFORMATION

Important Safety Information you should know about NAYZILAM® (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 continue to 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
- feeling agitated or restless
- · acting aggressive, being angry, or violent
- · attempts to commit suicide
- panic attacks
- · acting on dangerous impulses
- · new or worse depression

- trouble sleeping (insomnia)
- 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 patients 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 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. Taking NAYZILAM late in pregnancy may cause
  your baby to have symptoms of sedation (breathing problems, sluggishness, low muscle tone),
  and/or withdrawal symptoms (jitteriness, irritability, restlessness, shaking, excessive crying,
  feeding problems).
- are breastfeeding or plan to breastfeed. Breastfeeding during treatment with NAYZILAM may cause your baby to have sleepiness, feeding problems, and decreased weight gain.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

#### 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.
- 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

runny nose

· throat irritation

headache

· nasal discomfort

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.

Please see additional patient information in the Medication Guide. This information does not take the place of talking with your healthcare provider about your condition or your treatment. For more information, go to www.NAYZILAM.com or call 1-844-599-2273.



## **PATIENT SUPPORT**

#### **GET A TRAINING KIT**

You can sign up to receive a NAYZILAM training kit at www.NAYZILAM.com. It includes information to help you and your loved ones practice how to give the nasal spray, so everyone can feel reassured that they know what to do during a seizure cluster emergency.

The training kit includes one training device, which is meant to model the real NAYZILAM product in look and feel, but without any actual medicine. Holding the device and pressing the plunger will simulate what it feels like to use an actual device. This training device can be reset and practiced with again and again.

Please note: The actual device that contains medication can only be used one time.



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.

#### WHEN TO REPLACE NAYZILAM

Because seizure clusters can strike at anytime, it's always important to plan ahead. You should always have two spray devices on hand, so be sure to get a refill if you use one of the two devices that come in each box.

## CHECK EXPIRATION DATE

There are three places to check:

- On the peel pack
- · On the back of the device
- On the bottom panel of the product box

#### And remember to:

- Keep two spray devices at all times
- Take NAYZILAM with you wherever you go



Also, remember to check the expiration date on the NAYZILAM® (midazolam) nasal spray, CIV product label. If your product has or is about to expire, talk to your healthcare provider or pharmacist. Setting up a monthly check reminder in your calendar can help.



ucbCARES® is the hub for information on all UCB products. Reach out to our team of nurses, pharmacists, and customer service professionals to:

- · Ask questions about UCB products
- Report side effects or product quality concerns
- Get clinical trial information and support
- Find information on affording your UCB medication

#### **CONNECT WITH US**



1-844-599-CARE (2273)



www.askucbcares.com



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Visit www.NAYZILAM.com to learn more about treatment with NAYZILAM.

## **SAVINGS PROGRAM**

#### ELIGIBLE PATIENTS MAY PAY AS LITTLE AS \$20 FOR NAYZILAM\*

Sign up for a NAYZILAM Patient Savings Card to start saving on your prescription.

#### TO CHECK YOUR ELIGIBILITY AND GET STARTED:



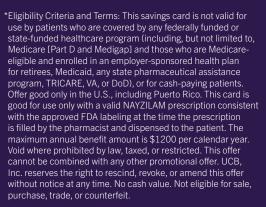
Visit www.NAYZILAM.com/savings



Text "JOINNAYZ" to 50566 to sign up for a **NAYZILAM Patient Savings Card and SMS** product reminder alerts<sup>†</sup>



Call 1-888-786-5879



<sup>†</sup>Message and data rates may apply. Four (4) messages per month.







## STOP SEIZURE **CLUSTERS QUICKLY** WITH NAYZILAM

Now you can feel confident knowing that you can stop a seizure cluster when it strikes and get back to your day.

#### IMPORTANT SAFETY INFORMATION

US-P-NZ-SC-2200119

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

Please talk to your healthcare provider if you have any questions or concerns about NAYZILAM.

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