HELP STUDENTS

get back to class

BE PREPARED TO STOP SEIZURE CLUSTERS WITH NAYZILAM

NAYZILAM® (midazolam) nasal spray, CIV is a ready-to-administer nasal spray.

NAYZILAM is indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 12 years of age and older.

IMPORTANT SAFETY INFORMATION

Concomitant use of benzodiazepines, including NAYZILAM, and opioids may result in profound sedation, respiratory depression, coma, and death. The use of benzodiazepines, including NAYZILAM, exposes users to risks of abuse, misuse, and addiction, which can lead to overdose or death. The continued use of benzodiazepines may lead to clinically significant physical dependence. Although NAYZILAM is indicated only for intermittent use, if used more frequently than recommended, abrupt discontinuation or rapid dosage reduction of NAYZILAM may precipitate acute withdrawal reactions, which can be life-threatening. The most common adverse reactions (≥5% in any NAYZILAM treatment group) were somnolence, headache, nasal discomfort, throat irritation, and rhinorrhea.

Please see the complete Important Safety Information on the back cover and the accompanying full Prescribing Information. You can also visit www.NAYZILAM.com.

Nayzilam® CIV
(midazolam) nasal spray

Seizure clusters can happen at almost any time, so being prepared is key. NAYZILAM is a nasal spray that can be used to treat seizure clusters anywhere during the school day.

NAYZILAM is a ready-to-administer nasal spray that may be administered:

- **By a non-healthcare professional, such as a teacher**
- **During or after a seizure within a cluster**
- **Without the need to remove a student's clothing**

STOP SEIZURE CLUSTERS FAST[1] SO THEY CAN

get back to class

In a clinical trial, NAYZILAM helped patients to stop a seizure cluster in 10 minutes and return to function within 90 minutes.[1,2]

10 min

Stopped seizure clusters within 10 minutes and prevented further seizure activity for up to 6 hours*[1†]

90 min

Helped patients get back to feeling like themselves within 90 minutes*[2‡]

24 hours

More patients had no seizure recurrence for 24 hours[1,3]

IMPORTANT SAFETY INFORMATION

NAYZILAM may cause an increased CNS-depressant effect when used with alcohol or other CNS depressants. Concomitant use with moderate or strong CYP3A4 inhibitors may result in prolonged sedation due to a decrease in plasma clearance of midazolam. Antiepileptic drugs, including NAYZILAM, increase the risk of suicidal ideation and behavior. Midazolam is associated with a high incidence of partial or complete impairment of recall for the next several hours. Benzodiazepines, including NAYZILAM, can increase intraocular pressure in patients with glaucoma. Use of NAYZILAM during pregnancy can result in neonatal sedation and/or neonatal withdrawal.

Please see the complete safety information on the back cover and the accompanying full Prescribing Information. You can also visit www.NAYZILAM.com.

*Baseline duration of seizure clusters in NAYZILAM arm was a median of 65 minutes (2.5–4320 mins)[3] †Primary endpoint of treatment success included two components: the termination of seizures within 10 minutes after the double-blind (first) dose and no recurrence of seizures between 10 min and 6 hours (double-blind observation period)1 ‡ Exploratory endpoint: Time to return to full baseline functionality as determined by caregiver.[3] • (range, 1.1–2.0 h)[2]

REFERENCES:

1. NAYZILAM® (midazolam): US prescribing information. Smyrna (GA): UCB, Inc. 2. UCB, Data on File. Proximagen, P261-401 Tables. 3. Detyniecki K, Van Ess PJ, Sequeira DJ, et al. Safety and efficacy of midazolam nasal spray in the outpatient treatment of patients with seizure clusters—a randomized, double-blind, placebo-controlled trial. *Epilepsia.* 2019;60:1797-1808.

Nayzilam® (midazolam) nasal spray

BE PREPARED TO USE NAYZILAM AND HELP YOUR STUDENT GET *back to class*

First Dose: One 5 mg spray in one nostril

Second Dose (if needed): An additional 5 mg dose may be administered after 10 minutes in the other nostril

Do not give more than 2 doses to treat a seizure cluster

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

HOW TO USE NAYZILAM (midazolam) NASAL SPRAY CIV

Please see the full instructions for use in the Prescribing Information and discuss with the student and their parent or caregiver. After peeling open the blister pack, follow the steps below. Remember to throw away (dispose of) the nasal spray device and blister packaging.

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.

CONSIDERATIONS PRIOR TO TREATMENT WITH NAYZILAM[1]

- For patients at increased risk of respiratory depression from benzodiazepines, administration under healthcare professional supervision should be considered prior to treatment; this administration may be performed in the absence of a seizure episode.
- Prior to treatment, the healthcare professional should instruct the individual administering on how to identify seizure clusters and use the product appropriately.
- Benzodiazepines, including NAYZILAM, can increase intraocular pressure in patients with glaucoma. NAYZILAM may be used in patients with open-angle glaucoma only if they are receiving appropriate therapy. NAYZILAM is contraindicated in patients with narrow-angle glaucoma.
- Concomitant use of NAYZILAM with moderate or strong CYP3A4 enzyme inhibitors may result in prolonged sedation. Caution patients against engaging in hazardous occupations requiring mental alertness, until they have completely returned to their level of baseline functioning.

Please see the full Prescribing Information for all instructions prior to dosing. Please see the complete safety information on the back cover and the accompanying full Prescribing Information. You can also visit www.NAYZILAM.com.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
NAYZILAM is contraindicated in patients with acute narrow-angle glaucoma.

RISKS FROM CONCOMITANT USE WITH OPIOIDS
Concomitant use of benzodiazepines, including NAYZILAM, and opioids may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing of these drugs for patients for whom alternative treatment options are inadequate. Limit dosages and durations to the minimum required. Follow patients for signs and symptoms of respiratory depression and sedation.

ABUSE, MISUSE, AND ADDICTION
The use of benzodiazepines, including NAYZILAM, exposes users to risks of abuse, misuse, and addiction, which can lead to overdose or death. Abuse and misuse of benzodiazepines commonly involve concomitant use of other medications, alcohol, and/or illicit substances, which is associat-ed with an increased frequency of serious adverse outcomes. Before prescribing NAYZILAM and throughout treatment, assess each patient's risk for abuse, misuse, and addiction.

DEPENDENCE AND WITHDRAWAL REACTIONS AFTER USE OF NAYZILAM MORE FREQUENTLY THAN RECOMMENDED
The continued use of benzodiazepines may lead to clinically significant physical dependence. The risks of dependence and withdrawal increase with longer treatment duration and higher daily dose. Although NAYZILAM is indicated only for intermittent use, if used more frequently than recommended, abrupt discontinuation or rapid dosage reduction of NAYZILAM may precipitate acute withdrawal reactions, which can be life-threatening. For patients using NAYZILAM more frequently than recommended, to reduce the risk of withdrawal reactions, use a gradual taper to discontinue NAYZILAM.

RISKS OF CARDIORESPIRATORY ADVERSE REACTIONS
Serious cardiorespiratory adverse reactions have occurred after administration of midazolam. Warn patients and caregivers about the risks of respiratory depression, cardiac and respiratory arrest. Respiratory depression was observed with the administration of NAYZILAM during clinical trials. Cardiac or respiratory arrest caused by NAYZILAM was not reported during clinical trials.

CENTRAL NERVOUS SYSTEM DEPRESSION FROM CONCOMITANT USE WITH OTHER CENTRAL NERVOUS SYSTEM DEPRESSANTS, OR MODERATE OR STRONG CYP3A4 INHIBITORS
Drug products containing midazolam, including NAYZILAM, have a central nervous system (CNS) depressant effect.

Risks from Concomitant Use with Other CNS Depressants
NAYZILAM may cause an increased CNS-depressant effect when used with alcohol or other CNS depressants (e.g., opioids). Warn patients and caregivers that the use of NAYZILAM in combination with alcohol or other CNS depressant drugs may increase the risk of hypoventilation, airway obstruction, desaturation, or apnea and may contribute to profound and/or prolonged drug effect.

Risks from Concomitant Use with Moderate or Strong CYP3A4 Inhibitors
Concomitant use of NAYZILAM with moderate or strong CYP3A4 enzyme inhibitors may result in prolonged sedation because of a decrease in plasma clearance of midazolam. Caution patients against engaging in hazardous occupations requiring mental alertness, such as operating machinery, driving a motor vehicle or riding a bicycle until they have completely returned to their level of baseline functioning.

SUICIDAL BEHAVIOR AND IDEATION
Antiepileptic drugs (AEDs), including NAYZILAM, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Monitor patients treated with NAYZILAM for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Advise patients and caregivers to be alert for these behavioral changes and to immediately report them to the healthcare provider.

IMPAIRED COGNITIVE FUNCTION
Midazolam, including NAYZILAM, is associated with a high incidence of partial or complete impairment of recall for several hours following an administered dose. Counsel patients on when they can engage in activities requiring complete mental alertness, operate hazardous machinery, or drive a motor vehicle after taking NAYZILAM.

GLAUCOMA
Benzodiazepines, including NAYZILAM, can increase intraocular pressure in patients with glaucoma. NAYZILAM may be used in patients with open-angle glaucoma only if they are receiving appropriate therapy. NAYZILAM is contraindicated in patients with narrow-angle glaucoma.

NEONATAL SEDATION AND WITHDRAWAL SYNDROME
Use of NAYZILAM late in pregnancy can result in sedation (respiratory depression, lethargy, hypotonia) and/or withdrawal symptoms (hyperreflexia, irritability, restlessness, tremors, inconsolable crying, and feeding difficulties) in the neonate. Monitor neonates exposed to NAYZILAM during pregnancy or labor for signs of sedation and monitor neonates exposed to NAYZILAM during pregnancy for signs of withdrawal; manage these neonates accordingly.

ADVERSE REACTIONS
In the randomized, double-blind, placebo-controlled trial, the most common adverse reactions (≥5% in any NAYZILAM treatment group) were somnolence, headache, nasal discomfort, throat irritation, and rhinorrhea.
NAYZILAM is a Schedule IV controlled substance.

Please see the accompanying full Prescribing Information or visit www.NAYZILAM.com.

NAYZILAM® is a registered trademark of the UCB Group of Companies.