

# Medication Guide

## Diazepam Tablets, USP

(dye az' e pam)



### What is the most important information I should know about diazepam tablets?

- **Diazepam tablets are 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.**
- **Diazepam tablets 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 diazepam tablets affect you.
  - Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking diazepam tablets without first talking to your healthcare provider. When taken with alcohol or drugs that cause sleepiness or dizziness, diazepam tablets may make your sleepiness or dizziness much worse.
  - Do not take more diazepam tablets than prescribed.

### What are diazepam tablets?

- Diazepam tablets are a prescription medicine used:
  - to treat anxiety disorders
  - for the short-term relief of the symptoms of anxiety
  - to relieve the symptoms of alcohol withdrawal including agitation, shakiness (tremor), sudden and severe mental or nervous system changes (delirium tremens) and seeing or hearing things that others do not see or hear (hallucinations)
  - along with other medicines for the relief of muscle spasms
  - along with other medicines to treat seizure disorders
- **Diazepam tablets are a federal controlled substance (C-IV) because it can be abused or lead to dependence.**

Keep diazepam tablets in a safe place to prevent misuse and abuse. Selling or giving away diazepam tablets may harm others, and is against the law. Tell your healthcare provider if you have abused or been dependent on alcohol, prescription medicines or street drugs.
- It is not known if diazepam tablets are safe and effective in children under 6 months of age.
- It is not known if diazepam tablets are safe and effective for use longer than 4 months.

### Do not take diazepam tablets if you:

- are allergic to diazepam or any of the ingredients in diazepam tablets. See the end of this Medication Guide for a complete list of ingredients in diazepam tablets.
- have a disease that can cause muscle weakness called myasthenia gravis
- have severe breathing problems (severe respiratory insufficiency)
- have severe liver problems
- have a sleep problem called sleep apnea syndrome

### Before you take diazepam tablets, tell your healthcare provider about all of your medical conditions, including if you:

- have or have had depression, mood problems, or suicidal thoughts or behavior
- have lung disease or breathing problems
- have liver or kidney problems
- are pregnant or plan to become pregnant. Diazepam tablets may harm your unborn baby. You and your healthcare provider should decide if you should take diazepam tablets while you are pregnant.
- are breastfeeding or plan to breastfeed. Diazepam 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 take diazepam tablets. Do not breastfeed while taking diazepam tablets.

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

Taking diazepam tablets with certain other medicines can cause side effects or affect how well diazepam tablets or the other medicines work. Do not start or stop other medicines without talking to your healthcare provider.

### How should I take diazepam tablets?

- Take diazepam tablets exactly as your healthcare provider tells you to take it. Your healthcare provider will tell you how many diazepam tablets to take and when to take it.
- Talk to your healthcare provider about slowly stopping diazepam tablets to avoid withdrawal symptoms.
- If you take too many diazepam tablets, call your healthcare provider or go to the nearest hospital emergency room right away.

### What should I avoid while taking diazepam tablets?

- Diazepam tablets can cause you to be drowsy. Do not drive a car or operate heavy machinery until you know how diazepam tablets affect you.
- You should not drink alcohol while taking diazepam tablets. Drinking alcohol can increase your chances of having serious side effects.

### What are the possible side effects of diazepam tablets?

#### Diazepam tablets may cause serious side effects, including:

- **See “What is the most important information I should know about diazepam tablets?”**
- **Seizures.** Taking diazepam tablets with other medicines used to treat epilepsy can cause an increase in the number or severity of grand mal seizures.
- **Withdrawal symptoms.** You may have withdrawal symptoms if you stop taking diazepam tablets suddenly. Withdrawal symptoms can be serious and include seizures. Mild withdrawal symptoms include a depressed mood and trouble sleeping. Talk to your healthcare provider about slowly stopping diazepam tablets to avoid withdrawal symptoms.
- **Like other antiepileptic drugs, diazepam tablets 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 | ○ attempts to commit suicide                          | ○ new or worse depression                    |
| ○ new or worse anxiety            | ○ feeling agitated or restless                        | ○ panic attacks                              |
| ○ trouble sleeping (insomnia)     | ○ new or worse irritability                           | ○ acting aggressive, being angry, or violent |
| ○ acting on dangerous impulses    | ○ an extreme increase in activity and talking (mania) | ○ other unusual changes in behavior or mood  |

#### How can I watch for early symptoms of suicidal thoughts and 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.

- **Abuse and dependence.** Taking diazepam tablets can cause physical and psychological dependence. Physical and psychological dependence is not the same as drug addiction. Your healthcare provider can tell you more about the differences between physical and psychological dependence and drug addiction.

#### The most common side effects of diazepam tablets include:

- |                   |  |
|-------------------|--|
| • drowsiness      | • fatigue                                    |
| • muscle weakness | • loss of control of body movements (ataxia) |

These are not all the possible side effects of diazepam tablets. **Call your doctor for medical advice about side effects.**

**You may report side effects to FDA at 1-800-FDA-1088.** You may also report side effects to Mylan Pharmaceuticals Inc. at 1-877-446-3679 (1-877-4-INFO-RX).

#### How should I store diazepam tablets?

- Store diazepam tablets in a tightly closed container at 20° to 25°C (68° to 77°F). Protect from light.
- **Keep diazepam tablets and all medicines out of the reach of children.**

#### General information about the safe and effective use of diazepam tablets.

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

#### What are the ingredients in diazepam tablets?

**Active ingredient:** diazepam

**Inactive ingredients:** colloidal silicon dioxide, magnesium stearate, microcrystalline cellulose, pregelatinized starch (corn) and sodium lauryl sulfate. The 5 mg tablets also contain FD&C Yellow No. 6 Aluminum Lake. The 10 mg tablets also contain FD&C Blue No. 1 Aluminum Lake and D&C Yellow No. 10 Aluminum Lake.

**Manufactured by:** Mylan Pharmaceuticals Inc., Morgantown, WV 26505 U.S.A.

For more information, call Mylan Pharmaceuticals Inc. at 1-877-446-3679 (1-877-4-INFO-RX).

This Medication Guide has been approved by the U.S. Food and Drug Administration



**Mylan Pharmaceuticals Inc.**  
Morgantown, WV 26505 U.S.A.

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