

MEDICATION GUIDE
DIAZEPAM TABLETS, USP
(diazepam) tablets, C-IV

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

- **DIAZEPAM 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 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 DIAZEPAM with opioids affects you.**
- **Risk of abuse, misuse, and addiction.** There is a risk of abuse, misuse, and addiction with benzodiazepines, including DIAZEPAM, 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 DIAZEPAM.** 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 get any of these serious side effects.**
 - **You can develop an addiction even if you take DIAZEPAM exactly as prescribed by your healthcare provider.**
 - **Take DIAZEPAM exactly as your healthcare provider prescribed.**
 - Do not share your DIAZEPAM with other people.
 - Keep DIAZEPAM in a safe place and away from children.
- **Physical dependence and withdrawal reactions.** DIAZEPAM can cause physical dependence and withdrawal reactions.
 - **Do not suddenly stop taking DIAZEPAM.** Stopping DIAZEPAM 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 get 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 take more DIAZEPAM than prescribed or take DIAZEPAM for longer than prescribed.

What is DIAZEPAM?

- DIAZEPAM is 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 is a federal controlled substance (C-IV) because it contains diazepam that can be abused or lead to dependence.** Keep DIAZEPAM in a safe place to prevent misuse and abuse. Selling or giving away DIAZEPAM 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 is safe and effective in children under 6 months of age.
- It is not known if DIAZEPAM is safe and effective for use longer than 4 months.

Do not take DIAZEPAM if you:

- are allergic to diazepam or any of the ingredients in DIAZEPAM. See the end of this Medication Guide for a complete list of ingredients in DIAZEPAM.
- 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, 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.
 - Taking DIAZEPAM 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).

- Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with DIAZEPAM.
- There is a pregnancy registry for women who take DIAZEPAM during pregnancy. The purpose of the registry is to collect information about the health of you and your baby. If you become pregnant during treatment with DIAZEPAM, talk to your healthcare provider about registering with the National Pregnancy Registry for Psychiatric Medications. You can register by calling 1-866-961-2388 or visiting <https://womensmentalhealth.org/pregnancyregistry/>.
- are breastfeeding or plan to breastfeed. DIAZEPAM passes into your breast milk.
 - Talk to your healthcare provider about the best way to feed your baby if you take DIAZEPAM.
 - Breastfeeding is not recommended during treatment with DIAZEPAM.

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

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

How should I take DIAZEPAM?

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

What are the possible side effects of DIAZEPAM? DIAZEPAM may cause serious side effects, including:

- **See “What is the most important information I should know about DIAZEPAM?”**
- **Seizures.** Taking DIAZEPAM with other medicines used to treat epilepsy can cause an increase in the number or severity of grand mal seizures.
- **DIAZEPAM 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 affects you.
 - **Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking DIAZEPAM without first talking to your healthcare provider.** When taken with alcohol or drugs that cause sleepiness or dizziness, DIAZEPAM may make your sleepiness or dizziness much worse.
- **Like other antiepileptic drugs, DIAZEPAM 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
- new or worse depression

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

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.

The most common side effects of DIAZEPAM include:

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

These are not all the possible side effects of DIAZEPAM. 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 Chartwell RX, LLC. at 1-845-232-1683.

How should I store DIAZEPAM?

- Store DIAZEPAM in a tightly closed container at room temperature between 68°F to 77°F (20°C to 25°C) and out of the light.
- Keep DIAZEPAM and all medicines out of the reach of children

General information about the safe and effective use of DIAZEPAM.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use DIAZEPAM for a condition for which it was not prescribed. Do not give DIAZEPAM 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 that is written for health professionals.

What are the ingredients in DIAZEPAM?

Active ingredient: diazepam

Inactive ingredients: Inactive ingredients for 2 mg, 5 mg or 10 mg includes: lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone and pregelatinized starch.

Manufactured For:

Chartwell RX, LLC.
Congers, NY 10920

L71795

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For more information, call. 1-845-232-1683.

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