

MEDICATION GUIDE
VALIUM (VAL-ee-um)
(diazepam)
tablets, C-IV

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

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

What is VALIUM?

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

Do not take VALIUM if you:

- are allergic to diazepam or any of the ingredients in VALIUM. See the end of this Medication Guide for a complete list of ingredients in VALIUM.
- 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 VALIUM, 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. VALIUM may harm your unborn baby. You and your healthcare provider should decide if you should take VALIUM while you are pregnant.
- are breastfeeding or plan to breastfeed. VALIUM 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 VALIUM. Do not breastfeed while taking VALIUM.

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

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

How should I take VALIUM?

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

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

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

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| • thoughts about suicide or dying | • attempts to commit suicide |
| • new or worse depression | • new or worse anxiety or irritability |
| • feeling agitated or restless | • an extreme increase in activity and talking (mania) |
| • trouble sleeping (insomnia) | • new or worse panic attacks |
| • acting aggressive, being angry or violent | • acting on dangerous impulses |
| • 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.

The most common side effects of VALIUM include:

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

These are not all the possible side effects of VALIUM. 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 Genentech at 1-888-835-2555.

How should I store VALIUM?

- Store VALIUM 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 VALIUM and all medicines out of the reach of children.

General information about the safe and effective use of VALIUM.

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

What are the ingredients in VALIUM?

Active ingredient: diazepam

Inactive ingredients: anhydrous lactose, corn starch, pregelatinized starch and calcium stearate

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For more information, go to www.gene.com/patients/medicines/Valium or call 1-877-436-3683.