

## Medication Guide

### MEDICATION GUIDE

**Diazepam *Intensol*<sup>TM</sup> Oral Solution (Concentrate), CIV  
25 mg/ 5 mL (5 mg/mL)  
(dye az' e pam)**

#### **What is the most important information I should know about Diazepam *Intensol*<sup>TM</sup> Oral Solution?**

- **Diazepam *Intensol*<sup>TM</sup> Oral Solution is a benzodiazepine medicine. Taking benzodiazepines with opioid medicines, alcohol, or other central nervous system depressants (CNS) (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 *Intensol*<sup>TM</sup> Oral Solution with opioids affects you.

- **Risk of abuse, misuse, and addiction.** There is a risk of abuse, misuse, and addiction with benzodiazepines, including Diazepam *Intensol*<sup>TM</sup> Oral Solution, 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 *Intensol*<sup>TM</sup> Oral Solution.** 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 *Intensol*<sup>TM</sup> Oral Solution exactly as prescribed by your healthcare provider.**
  - **Take Diazepam *Intensol*<sup>TM</sup> Oral Solution exactly as your healthcare provider prescribed.**
  - Do not share your Diazepam *Intensol*<sup>TM</sup> Oral Solution with other people.
  - Keep Diazepam *Intensol*<sup>TM</sup> Oral Solution in a safe place and away from children.
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**Physical dependence and withdrawal reactions.** Diazepam *Intensol*<sup>TM</sup> Oral Solution can cause physical dependence and withdrawal reactions, especially if you continue to take Diazepam *Intensol*<sup>TM</sup> Oral Solution for several days to several weeks.

- **Do not suddenly stop taking Diazepam *Intensol*<sup>TM</sup> Oral Solution.** Stopping Diazepam *Intensol*<sup>TM</sup> Oral Solution 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 *Intensol*<sup>TM</sup> Oral Solution than prescribed.

### **What is Diazepam *Intensol*<sup>TM</sup> Oral Solution?**

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

**Do not take Diazepam *Intensol*<sup>TM</sup> Oral Solution if you:**

- are allergic to diazepam or any of the ingredients in Diazepam *Intensol*<sup>TM</sup> Oral Solution. See the end of this Medication Guide for a complete list of ingredients in Diazepam *Intensol*<sup>TM</sup> Oral Solution.
- 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 *Intensol*<sup>TM</sup> Oral Solution, 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 *Intensol*<sup>TM</sup> Oral Solution 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 *Intensol*<sup>TM</sup> Oral Solution.
- There is a pregnancy registry for women who take Diazepam *Intensol*<sup>TM</sup> Oral Solution 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 *Intensol*<sup>TM</sup> Oral Solution, 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 *Intensol*<sup>TM</sup> Oral Solution passes into your breast milk.

- Breastfeeding is not recommended during treatment with Diazepam *Intensol*<sup>TM</sup> Oral Solution
- Talk to your healthcare provider about the best way to feed your baby if you take Diazepam *Intensol*<sup>TM</sup> Oral Solution. Do not breastfeed while taking Diazepam *Intensol*<sup>TM</sup> Oral Solution.

**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 *Intensol*<sup>TM</sup> Oral Solution or the other medicines work. Do not start or stop other medicines without talking to your healthcare provider.

### **How should I take Diazepam *Intensol*<sup>TM</sup> Oral Solution?**

- Take Diazepam *Intensol*<sup>TM</sup> Oral Solution exactly as your healthcare provider tells you to take it. Your healthcare provider will tell you how much Diazepam *Intensol*<sup>TM</sup> Oral Solution to take and when to take it.
- Always use the calibrated oral syringe that comes with Diazepam *Intensol*<sup>TM</sup> Oral Solution to correctly measure your dose.

Fill the oral syringe to the level of the prescribed dose. For ease of administration, add dose to approximately 30 mL (1 g. oz) or more of juice or other liquid. May also be added to applesauce, pudding or other semi-solid foods. The drug-food mixture should be used immediately and not stored for future use. Keep the oral syringe provided for future use.

**Discard opened bottle after 90 days.**

- Talk to your healthcare provider about slowly stopping Diazepam *Intensol*<sup>TM</sup> Oral Solution to avoid withdrawal symptoms.
- If you take too much Diazepam *Intensol*<sup>TM</sup> Oral Solution, call your healthcare provider or go to the nearest hospital emergency room right away.

### **What are the possible side effects of Diazepam *Intensol*<sup>TM</sup> Oral Solution?**

**Diazepam *Intensol*<sup>TM</sup> Oral Solution may cause serious side effects, including:**

- See **“What is the most important information I should know about Diazepam *Intensol*<sup>TM</sup> Oral Solution?”**
- **Seizures.** Taking Diazepam *Intensol*<sup>TM</sup> Oral Solution with other medicines used to treat epilepsy can cause an increase in the number or severity of grand mal seizures.
- **Diazepam *Intensol*<sup>TM</sup> Oral Solution can make you sleepy or dizzy, and can slow your thinking and motor skills.**

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Do not drive, operate heavy machinery, or do other dangerous activities until you know how Diazepam *Intensol*<sup>TM</sup> Oral Solution affects you.

- Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking Diazepam *Intensol*<sup>TM</sup> Oral Solution without first talking to your healthcare provider. When taken with alcohol or drugs that cause sleepiness or dizziness, Diazepam *Intensol*<sup>TM</sup> Oral Solution may make your sleepiness or dizziness much worse.

- **Like other antiepileptic drugs, Diazepam *Intensol*<sup>TM</sup> Oral Solution 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 anxiety
- trouble sleeping (insomnia)
- acting on dangerous impulses
- attempts to commit suicide
- feeling agitated or restless
- new or worse irritability
- an extreme increase in activity and talking (mania)
- new or worse depression
- panic attacks
- acting aggressive, being angry, or violent
- 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 Diazepam *Intensol*<sup>TM</sup> Oral Solution include:**

- drowsiness
- fatigue

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

These are not all the possible side effects of Diazepam *Intensol*<sup>TM</sup> Oral Solution. 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 Hikma Pharmaceuticals USA Inc. at 1-800-962-8364

#### **How should I store Diazepam *Intensol*<sup>TM</sup> Oral Solution?**

- Store Diazepam *Intensol*<sup>TM</sup> Oral Solution in a tightly closed, light-resistant container at room temperature between 68°F to 77°F (20°C to 25°C). **Protect from light.**
- **Keep Diazepam *Intensol*<sup>TM</sup> Oral Solution and all medicines out of the reach of children.**

**General information about the safe and effective use of Diazepam *Intensol*<sup>TM</sup> Oral Solution.** Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Diazepam *Intensol*<sup>TM</sup> Oral Solution for a condition for which it was not prescribed. Do not give Diazepam *Intensol*<sup>TM</sup> Oral Solution 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 *Intensol*<sup>TM</sup> Oral Solution that is written for health professionals.

#### **What are the ingredients in Diazepam *Intensol*<sup>TM</sup> Oral Solution?**

**Active ingredient:**

Each mL of Diazepam *Intensol*<sup>TM</sup> Oral Solution contains 5 mg diazepam, USP and 19% alcohol.

**Inactive ingredients:**

alcohol, D&C Yellow No. 10, polyethylene glycol, propylene glycol, succinic acid and water.

**This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised November 2022**

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