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Dispense with Medication Guide available at: [www.ingenus.com/medguide/triazolam-tablets.pdf](http://www.ingenus.com/medguide/triazolam-tablets.pdf)

MEDICATION GUIDE Triazolam Tablets USP CIV (trye az’ oh lam)
<p><b>What is the most important information I should know about Triazolam Tablets?</b></p> <ul style="list-style-type: none"><li>• <b>Triazolam tablets are 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.</b> Get emergency help right away if any of the following happens:<ul style="list-style-type: none"><li>○ shallow or slowed breathing</li><li>○ breathing stops (which may lead to the heart stopping)</li><li>○ excessive sleepiness (sedation)</li></ul></li></ul> <p>Do not drive or operate heavy machinery until you know how taking triazolam tablets with opioids affects you.</p> <ul style="list-style-type: none"><li>• <b>Risk of abuse, misuse, and addiction.</b> There is a risk of abuse, misuse, and addiction with benzodiazepines, including triazolam which can lead to overdose and serious side effects including coma and death.<ul style="list-style-type: none"><li>○ <b>Serious side effects including coma and death have happened in people who have abused or misused benzodiazepines, including triazolam.</b> These serious side effects may also include delirium, paranoia, suicidal thoughts or actions, seizures, and difficulty breathing. <b>Call your healthcare provider or go to the nearest hospital emergency room right away if you get any of these serious side effects.</b></li><li>○ <b>You can develop an addiction even if you take triazolam tablets as prescribed by your healthcare provider.</b></li><li>○ <b>Take triazolam tablets exactly as your healthcare provider prescribed.</b></li><li>○ Do not share your triazolam tablets with other people.</li><li>○ Keep triazolam tablets in a safe place and away from children.</li></ul></li><li>• <b>Physical dependence and withdrawal reactions.</b> Triazolam can cause physical dependence and withdrawal reactions.<ul style="list-style-type: none"><li>○ <b>Do not suddenly stop taking triazolam tablets.</b> Stopping triazolam tablets 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. <b>Call your healthcare provider or go to the nearest hospital emergency room right away if you get any of these symptoms.</b></li><li>○ <b>Some people who suddenly stop benzodiazepines, have symptoms that can last for several weeks to more than 12 months,</b> 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.</li><li>○ 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.</li><li>○ Do not take more triazolam tablets than prescribed or take triazolam tablets for longer than prescribed.</li></ul></li><li>• After taking triazolam tablets, you may get up out of bed while not being fully awake and do an activity that you do not know you are doing. The next morning, you may not remember that you did anything during the night. You have a higher chance for doing these activities if you drink alcohol or take other medicines that make you sleepy with triazolam tablets. Reported activities include:<ul style="list-style-type: none"><li>○ driving a car (“sleep-driving”)      ○ having sex</li><li>○ making and eating food                ○ sleep-walking</li><li>○ talking on the phone</li></ul></li></ul> <p><b>Call your healthcare provider right away if you find out that you have done any of the above activities after taking triazolam tablets.</b></p> <p><b>What are Triazolam tablets?</b> Triazolam is a prescription medicine used in adults for the short-term treatment of a sleep problem called insomnia. Triazolam tablets is usually taken for 7 to 10 days.</p> <ul style="list-style-type: none"><li>• <b>Triazolam tablets are a federal controlled substance (CIV) because it contains triazolam that can be abused or lead to dependence.</b> Keep triazolam tablets in a safe place to prevent misuse and abuse. Selling or giving away triazolam 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.</li><li>• It is not known if triazolam is safe and effective in children.</li><li>• It is not known if triazolam is safe and effective for use longer than 2 to 3 weeks.</li></ul> <p><b>Do not take triazolam tablets if you:</b></p> <ul style="list-style-type: none"><li>• are allergic to triazolam, other benzodiazepines, or any of the ingredients in triazolam tablets. Severe allergic reactions including swelling of the tongue or throat, trouble breathing and throat closing have happened and may lead to death. Get medical help right away if you have an allergic reaction to triazolam tablets. See the end of this Medication Guide for a complete list of ingredients in triazolam tablets.</li><li>• take antifungal medicines including ketoconazole and itraconazole</li><li>• take a medicine to treat depression called nefazodone</li><li>• take medicines to treat human immunodeficiency virus (HIV)-1 infection called protease inhibitors.</li></ul> <p><b>Before you take triazolam tablets, tell your healthcare provider about all of your medical conditions, including if you:</b></p> <ul style="list-style-type: none"><li>• have a history of depression, mood problems, mental illness, suicidal thoughts or behavior</li><li>• have a history of drug or alcohol abuse or addiction</li><li>• have lung problems, breathing problems, or sleep apnea</li><li>• are pregnant or plan to become pregnant.<ul style="list-style-type: none"><li>○ Taking triazolam 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).</li><li>○ Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with triazolam.</li><li>○ There is a pregnancy registry for women who take triazolam 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 triazolam, 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 <a href="https://womensmentalhealth.org/pregnancyregistry/">https://womensmentalhealth.org/pregnancyregistry/</a>.</li></ul></li></ul>

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- are breastfeeding or plan to breastfeed. It is not known if triazolam can pass through your breast milk.
  - Breastfeeding during treatment with triazolam may cause your baby to have sleepiness, feeding problems, and decreased weight gain.
  - Talk to your healthcare provider about the best way to feed your baby if you take triazolam tablets.

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

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

**How should I take triazolam tablets?**

- Take triazolam tablets exactly as your healthcare provider tells you to take it.
- Take triazolam tablets right before you get into bed.
- Do not eat grapefruit or drink grapefruit juice during treatment with triazolam tablets.
- Call your healthcare provider if your insomnia worsens or is not better within 7 to 10 days of treatment with triazolam tablets. This may mean that there is another condition causing your sleep problem.
- If you take too much triazolam tablets, call your healthcare provider or have somebody drive you to the nearest hospital emergency room right away.

**What are the possible side effects of Triazolam tablets?**

**Triazolam tablets may cause serious side effects, including:**

- **See “What is the most important information I should know about triazolam tablets?”**
- **Increased daytime anxiety.**
- **Abnormal thoughts and behavior.** Symptoms include more outgoing or aggressive behavior than normal, confusion, agitation, hallucinations, worsening of depression, and suicidal thoughts or actions.
- **Memory loss**
- **Triazolam 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 triazolam tablets affect you.
  - Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking triazolam tablets without first talking to your healthcare provider. When taken with alcohol or drugs that cause sleepiness or dizziness, triazolam tablets may make your sleepiness or dizziness much worse.
- **Worsening depression.** Call your healthcare provider right away if you have any thoughts of suicide or dying or worsening depression.

**The most common side effects of Triazolam tablets include:**

- drowsiness
- light-headedness
- dizziness
- difficulty with coordination

Elderly people have an increased risk of dose related side effects during treatment with triazolam tablets.

These are not all the possible side effects of triazolam tablets.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**How should I store Triazolam Tablets, USP?**

- Store triazolam tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- **Keep triazolam tablets and all medicines out of the reach of children**

**General information about the safe and effective use of triazolam tablets.**

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

**What are the ingredients in Triazolam Tablets, USP?**

**Active Ingredient:** Triazolam, USP

**Inactive Ingredients:** **0.125 mg** - lactose monohydrate, microcrystalline cellulose, pregelatinized starch, sodium starch glycolate, docusate sodium with sodium benzoate, colloidal silicon dioxide and magnesium stearate; **0.25 mg**- lactose monohydrate, microcrystalline cellulose, pregelatinized starch, sodium starch glycolate, FD&C Blue No. 1, docusate sodium with sodium benzoate, colloidal silicon dioxide and magnesium stearate.

**Manufactured for:**

Ingenus Pharmaceuticals, LLC  
Orlando, FL 32811

590305

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If you would like more information, call 1-877-748-1970.

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

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