

TRIAZOLAM- triazolam tablet

A-S Medication Solutions

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use TRIAZOLAM TABLETS safely and effectively. See full prescribing information for TRIAZOLAM TABLETS.

TRIAZOLAM tablets, for oral use, CIV

Initial U.S. Approval: 1982

WARNING: RISKS FROM CONCOMITANT USE WITH OPIOIDS

See full prescribing information for complete boxed warning.

Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death (5.1, 7.1).

- **Reserve concomitant prescribing for use in patients for whom alternative treatment options are inadequate.**
- **Limit dosages and durations to the minimum required.**
- **Follow patients for signs and symptoms of respiratory depression and sedation.**

INDICATIONS AND USAGE

Triazolam is a benzodiazepine indicated for the short-term treatment of insomnia (generally 7 to 10 days) in adults. (1)

DOSAGE AND ADMINISTRATION

- Adults: Recommended dosage is 0.25 mg once daily before bedtime. Maximum recommended dosage is 0.5 mg once daily (2.1)
- Geriatric patients: Reduce starting dosage to 0.125 mg once daily. May increase to 0.25 mg if no response. Geriatric patients should not exceed 0.25 mg once daily (2.2, 8.5)
- Triazolam tablets should not be prescribed in quantities exceeding a 1-month supply (2.1)

DOSAGE FORMS AND STRENGTHS

- Unscored Tablets: 0.125 mg and Scored Tablets: 0.25 mg (3)

CONTRAINDICATIONS

- Known hypersensitivity to triazolam or other benzodiazepines (4)
- Concomitant use with medications that significantly impair the oxidative metabolism mediated by cytochrome P450 3A (CYP 3A) including ketoconazole, itraconazole, nefazodone, and several human immunodeficiency virus (HIV) protease inhibitors (4, 5.7, 17)

WARNINGS AND PRECAUTIONS

- *Persistent or Worsening Insomnia:* Since sleep disturbances may be the presenting manifestation of a physical and/or psychiatric disorder, symptomatic treatment of insomnia should be initiated only after a careful evaluation of the patient. The failure of insomnia to remit after 7 to 10 days of treatment may indicate the presence of a primary psychiatric and/or medical illness that should be evaluated. (5.2)
- *“Sleep-driving” and Other Complex Behaviors:* Complex behaviors such as “sleep-driving” have been reported. The use of alcohol and other central nervous system (CNS) depressants with sedative-hypnotics appears to increase the risk, as well as doses exceeding the maximum recommended dose. (5.3)
- *CNS Manifestations:* An increase in daytime anxiety, abnormal thinking, and behavioral changes have been reported. Emergence of any new behavioral changes require careful and immediate evaluation. (5.4)
- *Effects on Driving and Operating Heavy Machinery:* Patients receiving triazolam should be cautioned against driving or operating heavy machinery, as well as avoiding concomitant use with alcohol and other CNS depressant drugs. (5.5)
- *Patients with Depression:* Caution should be exercised in patients with signs or symptoms of depression that could be intensified by hypnotic drugs. Prescribe the least number of tablets feasible to avoid intentional overdose. (5.7)
- *Tolerance/Withdrawal Phenomena:* Some loss of effectiveness and dependence may develop after nightly use for

more than a few weeks, which can lead to increased wakefulness and increased daytime anxiety or nervousness. Severe withdrawal effects and rebound insomnia may also occur. (5.8)

- *Neonatal Sedation and Withdrawal Syndrome:* Use of triazolam during pregnancy can result in neonatal sedation and neonatal withdrawal syndrome. (5.9, 8.1).

----- **ADVERSE REACTIONS** -----

Most common adverse reactions (incidence \geq 4% and twice placebo) are drowsiness, dizziness, light-headedness, and coordination disorder/ataxia (6.1).

To report SUSPECTED ADVERSE REACTIONS, contact West-Ward Pharmaceuticals Corp. at 1-800-962-8364 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----- **DRUG INTERACTIONS** -----

- Use with Opioids: Increase the risk of respiratory depression (7.1)
- Use with Other CNS Depressants: Produces additive CNS depressant effects (7.1)
- Use with CYP 3A4 Inhibitors: Increased risk of adverse reactions (4, 5.7, 7.1)

----- **USE IN SPECIFIC POPULATIONS** -----

Lactation: A lactating woman may pump and discard breast milk during treatment and for 28 hours after triazolam administration (8.2)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 11/2019

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FULL PRESCRIBING INFORMATION

WARNING: RISKS FROM CONCOMITANT USE WITH OPIOIDS

Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death [see Warnings and Precautions (5.1), Drug Interactions (7.1)].

- **Reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate.**
- **Limit dosages and durations to the minimum required.**
- **Follow patients for signs and symptoms of respiratory depression and sedation.**

1 INDICATIONS AND USAGE

Triazolam is indicated for the short-term treatment of insomnia (generally 7 to 10 days) in adults.

2 DOSAGE AND ADMINISTRATION

2.1 Dosing Information

The recommended dosage is 0.25 mg once daily before bedtime. A dosage of 0.125 mg once daily may be sufficient for some patients (e.g., patients with low body weight). A dosage of 0.5 mg should be used only for patients who do not respond adequately to a trial of a lower dose. The maximum recommended dosage is 0.5 mg once daily.

Use the lowest effective dose for the patient as there are significant dose related adverse reactions.

Use of triazolam tablets for more than 3 weeks requires evaluation of the patient for a primary psychiatric or medical condition [see Warnings and Precautions (5.2, 5.4, 5.8)].

Prescriptions for triazolam tablets should be written for short-term use (7 to 10 days) and it should not be prescribed in quantities exceeding a 1-month supply.

2.2 Use in Geriatric Patients

In geriatric patients, the recommended dosage is 0.125 mg to 0.25 mg once daily. Initiate therapy at

0.125 mg once daily. The 0.25 mg dose should be used only for patients who do not respond to a trial of the lower dose. The maximum recommended dosage is 0.25 mg once daily. Elderly patients have an increased risk of dose related adverse reactions [see *Use in Specific Populations (8.5)*].

3 DOSAGE FORMS AND STRENGTHS

Triazolam Tablets USP are available as a 0.125 mg and 0.25 mg tablet.

- 0.125 mg tablet is supplied as a white, oval-shaped tablet with tablet identification “54 519” debossed on one side and plain on the other side.
- 0.25 mg tablet is supplied as a light blue, oval-shaped tablet, scored on one side with tablet identification “54 620” debossed on the other side.

4 CONTRAINDICATIONS

Triazolam is contraindicated in:

- Patients with known hypersensitivity to triazolam, any of component of triazolam tablets, or other benzodiazepines. Reactions consistent with angioedema (involving the tongue, glottis, or larynx), dyspnea, and throat closing have been reported and may be fatal.
- Concomitant administration of strong cytochrome P450 (CYP 3A) enzyme inhibitors (e.g., ketoconazole, itraconazole, nefazodone, lopinavir, ritonavir) [see *Warnings and Precautions (5.7)*, *Drug Interactions (7.1)*].

5 WARNINGS AND PRECAUTIONS

5.1 Risks from Concomitant Use with Opioids

Concomitant use of benzodiazepines, including triazolam, and opioids may result in profound sedation, respiratory depression, coma, and death. Because of these risks, reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate.

Observational studies have demonstrated that concomitant use of opioid analgesics and benzodiazepines increases the risk of drug-related mortality compared to use of opioids alone. If a decision is made to prescribe triazolam concomitantly with opioids, prescribe the lowest effective dosages and minimum durations of concomitant use, and follow patients closely for signs and symptoms of respiratory depression and sedation. In patients already receiving an opioid analgesic, prescribe a lower initial dose of triazolam than indicated in the absence of an opioid and titrate based on clinical response. If an opioid is initiated in a patient already taking triazolam, prescribe a lower initial dose of the opioid and titrate based upon clinical response.

Advise both patients and caregivers about the risks of respiratory depression and sedation when triazolam is used with opioids. Advise patients not to drive or operate heavy machinery until the effects of concomitant use with the opioid have been determined [see *Drug Interactions (7.1)*].

5.2 Persistent or Worsening Insomnia

Since sleep disturbances may be the presenting manifestation of a physical and/or psychiatric disorder, symptomatic treatment of insomnia should be initiated only after a careful evaluation of the patient. The failure of insomnia to remit after 7 to 10 days of treatment may indicate the presence of a primary psychiatric and/or medical illness that should be evaluated. Worsening of insomnia or the emergence of new thinking or behavior abnormalities may be the consequence of an unrecognized psychiatric or physical disorder. Such findings have emerged during the course of treatment with sedative-hypnotic drugs.

5.3 “Sleep-driving” and Other Complex Behaviors

Complex behaviors such as “sleep-driving” (i.e., driving while not fully awake after ingestion of a sedative-hypnotic, with amnesia for the event) have been reported with triazolam use. These events can occur in sedative-hypnotic-naïve as well as in sedative-hypnotic-experienced persons. Although behaviors such as sleep-driving may occur with sedative-hypnotics alone at recommended dosages, the use of alcohol and other central nervous system (CNS) depressants with sedative-hypnotics appears to increase the risk of such behaviors, as does the use of sedative-hypnotics at doses exceeding the maximum recommended dose. Due to the risk to the patient and the community, discontinuation of sedative-hypnotics should be strongly considered for patients who report a “sleep-driving” episode.

Other complex behaviors (e.g., preparing and eating food, making phone calls, or having sex) have been reported in patients who are not fully awake after taking a sedative-hypnotic, including triazolam. As with sleep-driving, patients usually do not remember these events.

5.4 Central Nervous System Manifestations

An increase in daytime anxiety has been reported for triazolam after as few as 10 days of continuous use. In some patients this may be a manifestation of interdose withdrawal. If increased daytime anxiety is observed during treatment, discontinuation of treatment may be advisable.

A variety of abnormal thinking and behavior changes have been reported to occur in association with the use of benzodiazepine hypnotics including triazolam. Some of these changes may be characterized by decreased inhibition, e.g., aggressiveness and extroversion that seem excessive, similar to that seen with alcohol and other CNS depressants (e.g., sedative/hypnotics). Other kinds of behavioral changes have also been reported, for example, bizarre behavior, agitation, hallucinations, depersonalization. In primarily depressed patients, the worsening of depression, including suicidal thinking, has been reported in association with the use of benzodiazepines [*see Warnings and Precautions (5.8)*].

Some adverse reactions reported in association with the use of triazolam such as drowsiness, dizziness, light-headedness, and amnesia appear to be dose related. More serious behavioral phenomena such as confusion, bizarre or abnormal behavior, agitation, and hallucinations may also be dose related, but this evidence is inconclusive. Therapy should be initiated at the lowest effective dose [*see Dosage and Administration (2.1)*].

It can rarely be determined with certainty whether a particular instance of the abnormal behaviors listed above is drug induced, spontaneous in origin, or a result of an underlying psychiatric or physical disorder. Nonetheless, the emergence of any new behavioral sign or symptom of concern requires careful and immediate evaluation.

Anterograde amnesia of varying severity and paradoxical reactions have been reported following recommended dosages of triazolam. Data from several sources suggest that anterograde amnesia may occur at a higher rate with triazolam than with other benzodiazepine hypnotics.

Cases of “traveler’s amnesia” have been reported by individuals who have taken triazolam to induce sleep while traveling, such as during an airplane flight. In some of these cases, insufficient time was allowed for the sleep period prior to awakening and before beginning activity. Also, the concomitant use of alcohol may have been a factor in some cases.

5.5 Effects on Driving and Operating Heavy Machinery

Due to its depressant CNS effects, patients receiving triazolam should be cautioned against engaging in hazardous occupations requiring complete mental alertness such as operating machinery or driving a motor vehicle. For the same reason, patients should be cautioned about the concomitant use of alcohol and other CNS depressant drugs during treatment with triazolam.

5.6 Triazolam Interaction with Drugs that Inhibit Metabolism via Cytochrome P450 3A

The initial step in triazolam metabolism is hydroxylation catalyzed by CYP 3A. Drugs that inhibit this

metabolic pathway may have a profound effect on the clearance of triazolam.

Strong CYP 3A Inhibitors:

Triazolam is contraindicated in patients receiving strong inhibitors of CYP 3A such as ketoconazole, itraconazole, nefazodone, ritonavir, indinavir, nelfinavir, saquinavir, and lopinavir [see *Contraindications (4), Drug Interactions (7.1)*].

Moderate and Weak CYP 3A Inhibitors:

Triazolam should be used with caution in patients receiving moderate or weak inhibitors of CYP 3A. If coadministered, consider dose reduction of triazolam.

Macrolide Antibiotics:

Coadministration of erythromycin increased the maximum plasma concentration, decreased clearance and increased half-life of triazolam [see *Drug Interactions (7.1), Clinical Pharmacology (12.3)*]; caution and consideration of appropriate triazolam dose reduction are recommended. Similar caution should be observed during coadministration with clarithromycin and other macrolide antibiotics.

Cimetidine:

Coadministration of cimetidine increased the maximum plasma concentration, decreased clearance and increased half-life of triazolam [see *Drug Interactions (7.1), Clinical Pharmacology (12.3)*]; caution and consideration of appropriate triazolam dose reduction are recommended.

5.7 Patients with Depression

Benzodiazepines may worsen depression. Consequently, appropriate precautions (e.g., limiting the total prescription size and increased monitoring for suicidal ideation) should be considered in patients with depression.

5.8 Tolerance/Withdrawal Phenomena

Some loss of effectiveness or adaptation to the sleep inducing effects of benzodiazepines, including triazolam, may develop after nightly use for more than a few weeks and there may be a degree of dependence that develops. Withdrawal phenomena with triazolam have included: 1) increased wakefulness during the last third of the night, and 2) the appearance of increased signs of daytime anxiety or nervousness.

Withdrawal effects can occur after discontinuing these drugs following use for only a week or two, but may be more common and more severe after longer periods of continuous use. A phenomena known as 'rebound insomnia' may occur after stopping triazolam. That is, on the first few nights after the drug is stopped, insomnia is actually worse than before the sleeping pill was given.

Other withdrawal phenomena following abrupt stopping of benzodiazepine sleeping pills range from mild unpleasant feelings to a major withdrawal syndrome which may include abdominal and muscle cramps, vomiting, sweating, tremor, and convulsions.

5.9 Neonatal Sedation and Withdrawal Syndrome

Use of triazolam during the later stages of pregnancy can result in sedation (respiratory depression, lethargy, hypotonia) and withdrawal symptoms (hyperreflexia, irritability, restlessness, tremors, inconsolable crying, and feeding difficulties) in the neonate. Observe newborns for signs of sedation and neonatal *withdrawal syndrome and manage accordingly* [see *Use in Specific Populations (8.1)*].

5.10 Compromised Respiratory Function

In patients with compromised respiratory function, respiratory depression and apnea have been reported. Closely monitor patients with compromised respiratory function. If signs and symptoms of respiratory depression or apnea occur, consider discontinuation.

6 ADVERSE REACTIONS

The following serious adverse reactions are discussed in greater detail in other sections:

- Risks from Concomitant Use with Opioids [see Warnings and Precautions (5.1)]
- Persistent or Worsening Insomnia [see Warnings and Precautions (5.2)]
- “Sleep-driving” and Other Complex Behaviors [see Warnings and Precautions (5.3)]
- Central Nervous System Manifestations [see Warnings and Precautions (5.4)]
- Effects on Driving and Operating Heavy Machinery [see Warnings and Precautions (5.5)]
- Patients with Depression [see Warnings and Precautions (5.7)]
- Tolerance/Withdrawal Phenomena [see Warnings and Precautions (5.8)]
- Compromised Respiratory Function [see Warnings and Precautions (5.10)]

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The incidences cited below are estimates of clinical reactions among 1003 subjects who participated in the short term (duration of 1 to 42 days) placebo-controlled clinical trials of triazolam.

Adverse reactions leading to discontinuation in two multi-dose placebo controlled clinical trials include coordination disorders, drowsiness, grogginess, somnolence, depression, restlessness, dizziness, lightheadedness, headache, nausea, visual disturbance, nervousness, abdominal distress, bladder trouble, aching limbs, backache, and blepharitis.

Table 1: Common Adverse Drug Reactions in 1% or More of Triazolam-Treated Subjects (and Greater than Placebo) Reported in Placebo-Controlled Clinical Trials

Event	Triazolam (N=1003) % Patients Reporting	Placebo (N=997) % Patients Reporting
Central Nervous System		
Drowsiness	14.0	6.4
Headache	9.7	8.4
Dizziness	7.8	3.1
Nervousness	5.2	4.5
Light-headedness	4.9	0.9
Coordination disorders/ataxia	4.6	0.8
Gastrointestinal		

Nausea/vomiting	4.6	3.7
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In addition to the common reactions enumerated above in Table 1, the following adverse reactions have been reported at an incidence of 0.9% to 0.5%: euphoria, tachycardia, tiredness, confusional states/memory impairment, cramps/pain, depression, and visual disturbances.

Adverse reactions reported at an incidence less than 0.5% include: constipation, taste alterations, diarrhea, dry mouth, dermatitis/allergy, dreaming/nightmares, insomnia, paresthesia, tinnitus, dysesthesia, weakness, congestion, and death from hepatic failure in a patient also receiving diuretic drugs.

6.2 Postmarketing Experience

The following adverse reactions have been identified during post-approval use of triazolam. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

General Disorders and Administration Site Conditions: Paradoxical drug reaction, chest pain and fatigue

Gastrointestinal Disorders: Tongue discomfort, glossitis, stomatitis

Hepatobiliary Disorders: Jaundice

Injury, Poisoning and Procedural Complications: Fall

Metabolism and Nutrition Disorders: Anorexia

Nervous System Disorders: Anterograde amnesia, altered state of consciousness, dystonia, sedation, syncope, dysarthria and muscle spasticity

Psychiatric Disorders: Confusional state (disorientation, derealisation, depersonalization), mania, agitation, restlessness, irritability, sleep disorder and libido disorder, hallucination, delusion, aggression, somnambulism, and abnormal behavior

Renal and Urinary Disorders: Urinary retention and urinary incontinence

Reproductive System and Breast Disorders: Menstruation irregular

Skin and Subcutaneous Tissue Disorders: Pruritis

7 DRUG INTERACTIONS

7.1 Drugs Having Clinically Important Interactions with Triazolam

Table 2 includes clinically significant drug interactions with triazolam [see *Clinical Pharmacology* (12.3)].

Table 2: Clinically Important Drug Interactions with Triazolam

Opioids	
<i>Clinical implication</i>	The concomitant use of benzodiazepines and opioids increases the risk of respiratory depression because of actions at different receptor sites in the CNS that control respiration. Benzodiazepines interact at GABA _A sites and opioids interact primarily at mu receptors. When benzodiazepines and opioids are combined, the potential for benzodiazepines to significantly worsen opioid-related respiratory depression exists.
<i>Prevention or management</i>	Limit dosage and duration of concomitant use of triazolam and opioids, and monitor patients closely for respiratory depression and sedation [see

	<i>Warnings and Precautions (5.1)].</i>
<i>Examples</i>	Morphine, buprenorphine, hydromorphone, oxycodone, fentanyl, methadone, alfentanil, butorphanol, codeine, dihydrocodeine, meperidine, pentazocine, remifentanil, sufentanil, tapentadol, tramadol.
CNS Depressants	
<i>Clinical implication</i>	Triazolam produces additive CNS depressant effects when co-administered with other CNS depressants.
<i>Prevention or management</i>	Limit dosage and duration of triazolam during concomitant use with CNS depressants.
<i>Examples</i>	Psychotropic medications, anticonvulsants, antihistamines, ethanol, and other drugs which themselves produce CNS depression.
Strong Inhibitors of CYP 3A	
<i>Clinical implication</i>	Concomitant use of triazolam with strong CYP3A inhibitors has a profound effect on the clearance of triazolam, resulting in increased concentrations of triazolam and increased risk of adverse reactions [<i>see Clinical Pharmacology (12.3)]</i> .
<i>Prevention or management</i>	Do not administer triazolam with a strong CYP3A4 inhibitor [<i>see Contraindications (4), Warnings and Precautions (5.7)]</i> .
<i>Examples</i>	Ketoconazole, clarithromycin, grapefruit juice, itraconazole, nefazodone, and several HIV protease inhibitors (e.g. ritonavir, indinavir, nelfinavir, saquinavir and lopinavir).
Moderate and Weak Inhibitors of CYP 3A	
<i>Clinical implication</i>	Concomitant use of triazolam with moderate or weak inhibitors of CYP3A inhibitors may increase the concentrations of triazolam, resulting in increased risk of adverse reactions [<i>see Clinical Pharmacology (12.3)]</i> .
<i>Prevention or management</i>	Use with caution and consider appropriate dose reduction of triazolam when coadministered with moderate and weak CYP3A inhibitors [<i>see Warnings and Precautions (5.7)]</i> .
<i>Examples</i>	Macrolide antibiotics (such as erythromycin), cimetidine, isoniazid, oral contraceptives, ranitidine.
Interactions Based on Experience with Other Benzodiazepines or <i>in vitro</i> Studies with Triazolam	
<i>Clinical implication</i>	Available data from clinical studies of benzodiazepines other than triazolam, from <i>in vitro</i> studies with triazolam, or from <i>in vitro</i> studies with benzodiazepines other than triazolam suggest a possible drug interaction with triazolam [<i>see Clinical Pharmacology (12.3)]</i> .
<i>Prevention or management</i>	Caution is recommended during coadministration of triazolam with any of these drugs. [<i>see Warnings and Precautions (5.7)]</i> .
<i>Examples</i>	Fluvoxamine, diltiazem, verapamil, sertraline, paroxetine, ergotamine, cyclosporine, amiodarone, nifedipine, and nifedipine.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Exposure Registry:

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to triazolam during pregnancy. Healthcare providers are encouraged to register patients by calling the National Pregnancy Registry for Other Psychiatric Medications at 1-866-961-2388 or visiting online at <https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/othermedications/>.

Risk Summary:

Infants born to mothers using benzodiazepines during the later stages of pregnancy have been reported to experience symptoms of sedation and neonatal withdrawal (*see Clinical Considerations*)[*see Warnings and Precautions (5.9)*]. At this time, there is no clear evidence that triazolam exposure in early pregnancy can cause major birth defects (*see Data*).

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Clinical Considerations:

Fetal/Neonatal Adverse Reactions:

Benzodiazepines cross the placenta and may produce respiratory depression and sedation in neonates. Monitor neonates exposed to triazolam during pregnancy and labor for signs of sedation, respiratory depression, withdrawal, and feeding problems and manage accordingly [*see Warnings and Precautions (5.9)*].

Data:

Human Data:

Published data from observational studies on the use of benzodiazepines during pregnancy do not report a clear association with benzodiazepines and major birth defects. Although early studies reported an increased risk of congenital malformations with diazepam and chlordiazepoxide, there was no consistent pattern noted. In addition, the majority of more recent case-control and cohort studies of benzodiazepine use during pregnancy, which were adjusted for confounding exposures to alcohol, tobacco and other medications, have not confirmed these findings. At this time, there is no clear evidence that triazolam exposure in early pregnancy can cause major birth defects.

Infants exposed to benzodiazepines during the late third trimester of pregnancy or during labor have been reported to exhibit sedation and neonatal withdrawal symptoms.

Animal Data:

Oral administration of triazolam to pregnant rats and rabbits during the period of organogenesis caused skeletal developmental changes (variations and malformations) at maternally toxic doses in rats and at doses in rats and rabbits which are approximately equal to or greater than 200 times the maximum recommended human dose (MRHD) of 0.5 mg/day based on mg/m² body surface area. Oral administration of triazolam to male and female rats before mating, and continuing during gestation and lactation did not result in embryotoxicity at doses up to approximately 100 times the MRHD based on mg/m² body surface area, but did cause an increase in the number of stillbirths and postnatal pup mortalities at doses greater than or equal to approximately 40 times the MRHD based mg/m² body surface area. ¹⁴C-triazolam was administered orally to pregnant mice. Drug-related material appeared uniformly distributed in the fetus with ¹⁴C concentrations approximately the same as in the brain of the mother.

8.2 Lactation

Risk Summary:

There are no data on the presence of triazolam in human milk or the effects on milk production. There are reports of central nervous system depression (sedation, respiratory depression), withdrawal symptoms, and feeding problems in infants who are breastfed by mothers taking benzodiazepines (*see Clinical Considerations*). Triazolam and its metabolites are present in the milk of lactating rats (*see Data*). When a drug is present in animal milk, it is likely that the drug will be present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for triazolam and any potential adverse effects on the breastfed infant from triazolam or from the underlying maternal condition.

Clinical Considerations:

Infants exposed to triazolam through breast milk should be monitored for sedation, respiratory depression, withdrawal symptoms, and feeding problems. A lactating woman may consider interrupting breastfeeding and pumping and discarding breast milk during treatment and for 28 hours (approximately 5 elimination half-lives) after triazolam administration in order to minimize drug exposure to a breast fed infant.

Data:

Both triazolam and triazolam metabolites were detected in milk of rats. Lactating rats were orally administered 0.3 mg/kg ¹⁴C-triazolam; drug and metabolite levels were determined in milk collected at 6 and 24 hours after administration.

8.4 Pediatric Use

Safety and effectiveness of triazolam has not been established in pediatric patients.

8.5 Geriatric Use

Elderly patients exhibit higher plasma triazolam concentrations due to reduced clearance as compared with younger subjects at the same dose. Because elderly patients are especially susceptible to dose related adverse reactions and to minimize oversedation, the smallest effective dose should be used [*see Dosage and Administration (2.2), Clinical Pharmacology (12.3)*].

9 DRUG ABUSE AND DEPENDENCE

9.1 Controlled Substance

Triazolam tablets contain triazolam which is a Schedule IV controlled substance.

9.2 Abuse

Abuse and addiction are separate and distinct from physical dependence and tolerance. Abuse is characterized by misuse of the drug for non-medical purposes, often in combination with other psychoactive substances. Physical dependence is a state of adaptation that is manifested by a specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug and/or administration of an antagonist. Tolerance is a state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug's effects over time. Tolerance may occur to both the desired and undesired effects of drugs and may develop at different rates for different effects.

Addiction is a primary, chronic, neurobiological disease with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving. Drug addiction is a treatable disease, utilizing a multidisciplinary approach, but relapse is common.

Addiction-prone individuals (e.g. those with a history of drug addiction or alcoholism) should be under careful surveillance when receiving triazolam because of increased risk of abuse and dependence.

9.3 Dependence

Withdrawal symptoms, including: convulsions, tremor, abdominal and muscle cramps, vomiting, sweating, dysphoria, perceptual disturbances, and insomnia have occurred following abrupt discontinuance of benzodiazepines, including triazolam. The more severe symptoms are usually associated with higher dosages and longer usage, although patients at recommended dosages given for as few as 1 to 2 weeks can also have withdrawal symptoms and in some patients there may be withdrawal

symptoms (daytime anxiety, agitation) between nightly doses [see Warnings and Precautions (5.9)]. Consequently, abrupt discontinuation should be avoided and a gradual dosage tapering schedule is recommended in any patient taking more than the lowest dose for more than a few weeks. The recommendation for tapering is particularly important in any patient with a history of seizure.

The risk of dependence is increased in patients with a history of alcoholism, drug abuse, or in patients with marked personality disorders. Such dependence-prone individuals should be under careful surveillance when receiving triazolam. As with all hypnotics, repeat prescriptions should be limited to those who are under medical supervision.

10 OVERDOSAGE

Manifestations of overdose with triazolam include somnolence, confusion, impaired coordination, slurred speech, and ultimately, coma. Respiratory depression and apnea have been reported with overdoses of triazolam. Seizures have been reported after overdoses.

Death has been reported in association with overdoses of triazolam. In addition, fatalities have been reported in patients who have overdosed with a combination of a single benzodiazepine, including triazolam, and alcohol; benzodiazepine and alcohol levels seen in some of these cases have been lower than those usually associated with reports of fatality with either substance alone.

Respiration, pulse, and blood pressure should be monitored and supported by general measures when necessary. Immediate gastric lavage should be performed. An adequate airway should be maintained. Intravenous fluids may be administered.

Flumazenil may be useful in situations when an overdose with a benzodiazepine is known or suspected. Prior to the administration of flumazenil, necessary measures should be instituted to secure airway, ventilation and intravenous access. Flumazenil is intended as an adjunct to, not as a substitute for, proper management of benzodiazepine overdose. Patients treated with flumazenil should be monitored for re sedation, respiratory depression, and other residual benzodiazepine effects for an appropriate period after treatment. The prescriber should be aware of a risk of seizure in association with flumazenil treatment, particularly in long-term benzodiazepine users and in cyclic antidepressant overdose. The complete flumazenil package insert including Contraindications and Warnings and Precautions should be consulted prior to use.

Hemodialysis and forced diuresis are probably of little value. As with the management of intentional overdose with any drug, the physician should bear in mind that multiple agents may have been ingested by the patient.

In case of an overdose, consult a Certified Poison Control Center at 1-800-222-1222 for latest recommendations.

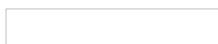
11 DESCRIPTION

Triazolam Tablets USP contain triazolam, a triazolobenzodiazepine.

Triazolam USP is a white to off-white powder, soluble in chloroform; slightly soluble in alcohol; and practically insoluble in ether and in water. It has a molecular weight of 343.2.

The chemical name for triazolam is 8-chloro-6-(*o*-chlorophenyl)-1-methyl-4*H*-s-triazolo-[4,3- α][1,4]benzodiazepine.

The structural formula is represented below:



Each triazolam tablet for oral administration, contains 0.125 mg or 0.25 mg of triazolam USP.

Inactive ingredients: **0.125 mg** - docusate sodium with sodium benzoate, lactose (anhydrous), magnesium stearate, microcrystalline cellulose, and pregelatinized starch; **0.25 mg** - docusate sodium with sodium benzoate, FD&C Blue No. 1, lactose (anhydrous), magnesium stearate, microcrystalline cellulose, and pregelatinized starch.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Triazolam is a benzodiazepine. Triazolam exerts its effect for the short-term treatment of insomnia through binding to the benzodiazepine site of the gamma-aminobutyric acid-A (GABA_A) receptors in the brain and enhances GABA-mediated synaptic inhibition.

12.3 Pharmacokinetics

Absorption:

Peak plasma levels of triazolam are reached within 2 hours following oral administration. Following recommended doses of triazolam tablets, triazolam peak plasma levels in the range of 1 to 6 ng/mL are seen. The plasma levels achieved are proportional to the dose given. In normal subjects treated for 7 days with four times the recommended dosage, there was no evidence of altered systemic bioavailability, rate of elimination, or accumulation.

Distribution:

Extremely high concentrations of triazolam do not displace bilirubin bound to human serum albumin *in vitro*.

Elimination:

Triazolam has a mean plasma elimination half-life in the range of 1.5 to 5.5 hours.

Metabolism:

The initial step in triazolam metabolism is cytochrome P450 3A (CYP 3A)-mediated hydroxylation to form 1- hydroxytriazolam and 4-hydroxytriazolam, which are subsequently conjugated to form glucuronides.

Excretion:

Triazolam and its metabolites, principally as conjugated glucuronides which are presumably inactive, are excreted primarily in the urine. Only small amounts of unmetabolized triazolam appear in the urine. The two primary metabolites accounted for 79.9% of urinary excretion. Urinary excretion appeared to be biphasic in its time course.

Specific Populations:

Geriatric Patients:

In a study of elderly (62 to 83 years old) versus younger subjects (21 to 41 years old) who received triazolam at the same dose levels (0.125 mg and 0.25 mg), the elderly experienced both greater sedation and impairment of psychomotor performance. These effects resulted largely from higher plasma concentrations of triazolam in the elderly.

Drug Interaction Studies:

The effect of other drugs on triazolam:

Macrolide Antibiotics:

Coadministration of erythromycin increased the maximum plasma concentration of triazolam by 46%,

decreased clearance by 53%, and increased half-life by 35%.

Cimetidine:

Coadministration of cimetidine increased the maximum plasma concentration of triazolam by 51%, decreased clearance by 55%, and increased half-life by 68%.

Isoniazid:

Coadministration of isoniazid increased the maximum plasma concentration of triazolam by 20%, decreased clearance by 42%, and increased half-life by 31%.

Oral Contraceptives:

Coadministration of oral contraceptives increased maximum plasma concentration by 6%, decreased clearance by 32%, and increased half-life by 16%.

Grapefruit Juice:

Coadministration of grapefruit juice increased the maximum plasma concentration of triazolam by 25%, increased the area under the concentration curve by 48%, and increased half-life by 18%.

Ranitidine:

Coadministration of ranitidine increased the maximum plasma concentration of triazolam by 30%, increased the area under the concentration curve by 27%, and increased half-life by 3.3%. Caution is recommended during coadministration with triazolam. Available data from clinical studies of benzodiazepines other than triazolam suggest a possible drug interaction with triazolam for the following: fluvoxamine, diltiazem, and verapamil. Data from *in vitro* studies of triazolam suggest a possible drug interaction with triazolam for the following: sertraline and paroxetine. Data from *in vitro* studies of benzodiazepines other than triazolam suggest a possible drug interaction with triazolam for the following: ergotamine, cyclosporine, amiodarone, nicardipine, and nifedipine.

The effect of triazolam on other drugs:

Warfarin:

Triazolam tablets 0.5 mg, in two separate studies, did not affect the prothrombin times or plasma warfarin levels in male volunteers administered sodium warfarin orally.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis:

No evidence of carcinogenic potential was observed in rats or mice administered triazolam in the diet for 24-months at doses greater than or equal to 900 times the MRHD of 0.5 mg, based on mg/m² body surface area.

Mutagenesis:

Triazolam was not mutagenic in the *in vitro* Ames bacterial reverse mutation assay, and no DNA damage was observed in an *in vitro* alkaline elution assay in Chinese hamster lung fibroblast cells.

Impairment of Fertility:

Female rats were administered triazolam in the diet for 14 days before cohabitation, during gestation, and until 21 days post parturition, and male rats for 60 days before cohabitation. No effects on mating or fertility were observed in rats up to 5 mg/kg/day which is approximately 100 times the MRHD of 0.5 mg/day, based on mg/m² body surface area.

16 HOW SUPPLIED/STORAGE AND HANDLING

Product: 50090-4733

NDC: 50090-4733-0 30 TABLET in a BOTTLE

NDC: 50090-4733-1 100 TABLET in a BOTTLE

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide).

Risks from Concomitant Use with Opioids:

Advise both patients and caregivers about the risks of potentially fatal respiratory depression and sedation when triazolam is used with opioids and not to use such drugs concomitantly unless supervised by a healthcare provider. Advise patients not to drive or operate heavy machinery until the effects of concomitant use with the opioid have been *determined [see Warnings and Precautions (5.1), Drug Interactions (7.1)]*.

“Sleep-driving” and Other Complex Behaviors:

There have been reports of people getting out of bed after taking a sedative-hypnotic and driving their cars while not fully awake, often with no memory of the event. Advise patients to report similar experiences to their healthcare provider immediately, since “sleep-driving” can be dangerous. This behavior is more likely to occur when sedative-hypnotics are taken with alcohol or other CNS depressants *[see Warnings and Precautions (5.3)]*. Other complex behaviors (e.g., preparing and eating food, making phone calls, or having sex) have been reported in patients who are not fully awake after taking a sedative hypnotic. As with sleep-driving, patients usually do not remember these events.

Effects on Driving and Operating Heavy Machinery:

Caution patients against driving a motor vehicle or operating heavy machinery until the effects of taking triazolam are determined due to its CNS depressant effects. Also advise patients to avoid the use of alcohol or other CNS depressants while taking triazolam *[see Warnings and Precautions (5.6)]*.

Patients with Depression:

Advise patients, their families and caregivers to look out for any signs of suicidality or worsening depression, and to inform the patient’s prescriber or healthcare provider immediately *[see Warnings and Precautions (5.8)]*.

Concomitant Medications:

Advise patients to inform their healthcare provider of all medicines they take, including prescription and nonprescription medicines, vitamins and herbal supplements *[see Drug Interactions (7.1)]*.

Grapefruit Juice:

Advise patients to avoid eating grapefruit or drinking grapefruit juice while taking triazolam *[see Drug Interactions (7.1)]*.

Pregnancy:

Benzodiazepines cross the placenta and may produce respiratory depression and sedation in neonates. Advise mothers using triazolam to monitor neonates for signs of sedation, respiratory depression, withdrawal, and feeding problems *[see Warnings and Precautions (5.9), Use in Specific Populations (8.1)]*.

Lactation:

Advise mothers using benzodiazepines to monitor neonates for signs of sedation, respiratory depression, withdrawal symptoms, and feeding problems. A lactating woman may consider pumping and discarding breastmilk during treatment and for 28 hours after triazolam administration to minimize drug

exposure to a breastfed infant [see Use in Specific Populations (8.2)].

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Pharmaceuticals Corp.**
Eatontown, NJ 07724

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MEDICATION GUIDE

Triazolam Tablets USP CIV (trye az' oh lam) Rx only

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

- Triazolam tablets are a benzodiazepine medicine. Benzodiazepines can cause severe drowsiness, breathing problems (respiratory depression), coma and death when taken with opioid medicines. 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:
 - driving a car (“sleep-driving”)
 - making and eating food
 - talking on the phone
 - having sex
 - sleep-walking

Call your healthcare provider right away if you find out that you have done any of the above activities after taking triazolam tablets.

- **Do not** take more triazolam tablets than prescribed or take triazolam tablets for longer than prescribed.

What are Triazolam Tablets?

Triazolam is a prescription medicine used in adults for the short-term treatment of a sleep problem called insomnia. Triazolam tablets are usually taken for 7 to 10 days.

- Triazolam is a federal controlled substance (CIV) because it can be abused or lead to dependence. 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.
- It is not known if triazolam is safe and effective in children.
- It is not known if triazolam is safe and effective for use longer than 2 to 3 weeks.

Do not take triazolam tablets if you:

- 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.

- take antifungal medicines including ketoconazole and itraconazole
- take a medicine to treat depression called nefazodone
- take medicines to treat human immunodeficiency virus (HIV)-1 infection called protease inhibitors.

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

- have a history of depression, mood problems, mental illness, suicidal thoughts or behavior
- have a history of drug or alcohol abuse or addiction
- have lung problems, breathing problems, or sleep apnea
- are pregnant or plan to become pregnant.
 - If you become pregnant while taking triazolam tablets, talk to your healthcare provider about registering with the National Pregnancy Registry for psychiatric medicines during pregnancy. You can register by calling 1-866-961-2388 or visit <https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/othermedications/>.
 - Babies born to mothers who take benzodiazepine medicines, including triazolam tablets, late in pregnancy may have symptoms of sedation, such as breathing problems, sluggishness, and low muscle tone (floppy baby syndrome), feeding problems and withdrawal symptoms.
- are breastfeeding or plan to breastfeed. It is not known if triazolam can pass through your breast milk. 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 should I avoid while taking triazolam tablets?

- Do not drive, operate heavy machinery, or do other dangerous activities until you know how triazolam tablets affects you.
- Do not drink alcohol or take other medicines that may make you sleepy or dizzy during treatment with triazolam tablets. When taken with alcohol or medicines that cause sleepiness or dizziness, triazolam tablets may make your sleepiness or dizziness much worse.

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**
- **Worsening depression.** Call your healthcare provider right away if you have any thoughts of suicide or dying or worsening depression.
- **Withdrawal symptoms.** You can have withdrawal symptoms after you stop taking triazolam tablets even if you have taken it for only a week or two. The withdrawal symptoms may be more common and severe after continuous use. Withdrawal symptoms include trouble sleeping, increased symptoms of daytime anxiety or nervousness, stomach and muscle cramps, vomiting, sweating, shakiness, and seizures. You may also have a symptom called “rebound insomnia” after you stop taking triazolam tablets. Rebound insomnia can happen on the first few nights after triazolam tablets is stopped and your sleep problems may be worse than before taking triazolam tablets. Talk to your healthcare provider about slowly stopping triazolam tablets.
- **Abuse and dependence.** 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.

The most common side effects of Triazolam tablets include:

- drowsiness
- dizziness
- lightheadedness
- 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 at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]
- **Keep Triazolam Tablets USP 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 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: docusate sodium with sodium benzoate, lactose (anhydrous), magnesium stearate, microcrystalline cellulose and pregelatinized starch; **0.25 mg:** docusate sodium with sodium benzoate, FD&C Blue No. 1, lactose (anhydrous), magnesium stearate, microcrystalline cellulose and pregelatinized starch.

Distr. by: **West-Ward
Pharmaceuticals Corp.**

Eatontown, NJ

For information, please call 1-800-962-8364.

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

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Revised October 2019

Triazolam



TRIAZOLAM

triazolam tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:50090- 4733(NDC:0054-4859)
Route of Administration	ORAL	DEA Schedule	CIV

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRIAZOLAM (UNII: 1HM943223R) (TRIAZOLAM - UNII:1HM943223R)	TRIAZOLAM	0.25 mg

Inactive Ingredients

Ingredient Name	Strength
DOCUSATE SODIUM/SODIUM BENZOATE (UNII: 656HXR6YXN)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	BLUE (light)	Score	2 pieces
Shape	OVAL	Size	8mm
Flavor		Imprint Code	54;620
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-4733-0	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/18/2019	
2	NDC:50090-4733-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/18/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074224	10/29/2018	

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-4733) , REPACK(50090-4733)

Revised: 11/2019

A-S Medication Solutions