



Drugs and Supplements

Lorazepam (Oral Route)

Description and Brand Names

US Brand Name

Ativan

Descriptions

Lorazepam Intensol

Lorazepam is used to treat anxiety disorders. It is also used for short-term relief of the symptoms of anxiety or anxiety caused by depression. Lorazepam is a benzodiazepine that works in the brain to relieve symptoms of anxiety. Benzodiazepines are central nervous system (CNS) depressants, which are medicines that slow down the nervous system.

This medicine is available only with your doctor's prescription.

This product is available in the following dosage forms:

- Tablet
- Solution

Before Using

In deciding to use a medicine, the risks of taking the medicine must be weighed against the good it will do. This is a decision you and your doctor will make. For this medicine, the following should be considered:

Allergies

Tell your doctor if you have ever had any unusual or allergic reaction to this medicine or any other medicines. Also tell your health care professional if you have any other types of allergies, such as to foods, dyes, preservatives, or animals. For non-prescription products, read the label or package ingredients carefully.

Pediatric

Appropriate studies have not been performed on the relationship of age to the effects of lorazepam in children younger than 12 years of age. Safety and efficacy have not been established.

Geriatric

Appropriate studies performed to date have not demonstrated geriatric-specific problems that would limit the usefulness of lorazepam in the elderly. However, elderly patients are more likely to have unwanted effects (eg, severe drowsiness or unsteadiness) and age-related kidney or liver problems, which may require caution and an adjustment in the dose.

Pregnancy

	Pregnancy Category	Explanation
All Trimesters	D	Studies in pregnant women have demonstrated a risk to the fetus. However, the benefits of therapy in a life threatening situation or a serious disease, may outweigh the potential risk.

Breastfeeding

Studies in women suggest that this medication poses minimal risk to the infant when used during breastfeeding.

Drug Interactions

Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. When you are taking this medicine, it is especially important that your healthcare professional know if you are taking any of the medicines listed below. The following interactions have been selected on the basis of their potential significance and are not necessarily all-inclusive.

Using this medicine with any of the following medicines is not recommended. Your doctor may decide not to treat you with this medication or change some of the other medicines you take.

- Flumazenil

Using this medicine with any of the following medicines is usually not recommended, but may be required in some cases. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines.

- Alfentanil
- Amobarbital
- Benzhydrocodone
- Bromazepam
- Bromopride
- Buprenorphine

- Butabarbital
- Butalbital
- Butorphanol
- Calcifediol
- Cannabidiol
- Carbinoxamine
- Carisoprodol
- Chloral Hydrate
- Chlorzoxazone
- Clobazam
- Codeine
- Dantrolene
- Dezocine
- Diacetylmorphine
- Difenoxin
- Dihydrocodeine
- Diphenoxylate
- Doxylamine
- Esketamine
- Ethchlorvynol
- Ethylmorphine
- Fentanyl
- Flibanserin
- Fospropofol
- Hydrocodone
- Hydromorphone
- Ketobemidone
- Levorphanol
- Lofexidine
- Loxapine
- Meclizine
- Meperidine
- Mephenesin
- Mephobarbital
- Meprobamate

- Meptazinol
- Metaxalone
- Methadone
- Methocarbamol
- Methohexital
- Metoclopramide
- Midazolam
- Mirtazapine
- Morphine
- Morphine Sulfate Liposome
- Nalbuphine
- Nicomorphine
- Opium
- Opium Alkaloids
- Orlistat
- Oxycodone
- Oxymorphone
- Papaveretum
- Paregoric
- Pentazocine
- Pentobarbital
- Periciazine
- Phenobarbital
- Piritramide
- Primidone
- Propofol
- Scopolamine
- Secobarbital
- Sodium Oxybate
- Sufentanil
- Tapentadol
- Thiopental
- Tilidine
- Tramadol
- Trazodone

- Zolpidem

Using this medicine with any of the following medicines may cause an increased risk of certain side effects, but using both drugs may be the best treatment for you. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines.

- Posaconazole
- Probenecid
- Pyrimethamine
- St John's Wort
- Theophylline
- Valproic Acid

Other Interactions

Certain medicines should not be used at or around the time of eating food or eating certain types of food since interactions may occur. Using alcohol or tobacco with certain medicines may also cause interactions to occur. The following interactions have been selected on the basis of their potential significance and are not necessarily all-inclusive.

Other Medical Problems

The presence of other medical problems may affect the use of this medicine. Make sure you tell your doctor if you have any other medical problems, especially:

- Alcohol abuse or
- Drug abuse or dependence or
- Lung or breathing problems (eg, COPD, sleep apnea) or
- Seizures, or history of—Use with caution. May make these conditions worse.
- Depression or
- Psychosis—Use is not recommended in patients with these conditions.
- Glaucoma, acute narrow-angle—Should not be used in patients with this condition.
- Kidney disease or
- Liver disease—Use with caution. The effects may be increased because of slower removal of the medicine from the body.

Proper Use

Take this medicine only as directed by your doctor. Do not take more of it, do not take it more often, and do not take it for a longer time than your doctor ordered.

This medicine should come with a Medication Guide. Read and follow these instructions carefully. Ask your doctor if you have any questions.

Swallow the tablet whole. Do not crush, break, or chew it.

Measure the oral liquid using the marked medicine dropper that comes with the package. Dilute each dose with water, juice, soda, applesauce and puddings.

Dosing

The dose of this medicine will be different for different patients. Follow your doctor's orders or the directions on the label. The following information includes only the average doses of this medicine. If your dose is different, do not change it unless your doctor tells you to do so.

The amount of medicine that you take depends on the strength of the medicine. Also, the number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are using the medicine.

- For oral dosage form (oral solution):
 - For anxiety:
 - Adults and children 12 years of age and older—2 to 6 milligrams (mg) in divided doses per day. Your doctor may adjust your dose as needed.
 - Older adults—At first, 1 to 2 mg in divided doses per day. Your doctor may adjust your dose as needed.
 - Children younger than 12 years of age—Use and dose must be determined by your doctor.
- For oral dosage form (tablets):
 - For anxiety:
 - Adults and children 12 years of age and older—At first, 2 to 3 milligrams (mg) in divided doses per day. Your doctor may adjust your dose as needed.
 - Older adults—At first, 1 to 2 mg in divided doses per day. Your doctor may adjust your dose as needed and tolerated.
 - Children younger than 12 years of age—Use and dose must be determined by your doctor.
 - For insomnia caused by anxiety or transient situational stress:
 - Adults and children 12 years of age and older—2 to 4 milligrams (mg) taken as a single dose at bedtime. Your doctor may adjust your dose as needed.
 - Children younger than 12 years of age—Use and dose must be determined by your doctor.

Missed Dose

If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

Storage

Store the medicine in a closed container at room temperature, away from heat, moisture, and direct light. Keep from freezing.

Keep out of the reach of children.

Do not keep outdated medicine or medicine no longer needed.

Ask your healthcare professional how you should dispose of any medicine you do not use.

Precautions

It is very important that your doctor check your or your child's progress at regular visits to see if this medicine is working and allow for changes in the dose. Blood tests may be needed to check for any unwanted effects.

Using this medicine while you are pregnant can harm your unborn baby. Use an effective form of birth control to keep from getting pregnant. If you think you have become pregnant while using the medicine, tell your doctor right away.

This medicine may be habit-forming. If you feel that the medicine is not working as well, do not use more than your prescribed dose. Call your doctor for instructions.

This medicine may cause drowsiness, trouble with thinking, trouble with controlling movements, or trouble with seeing clearly. Make sure you know how you react to this medicine before you drive, use machines, or do anything else that could be dangerous if you are not alert or able to think or see well.

Do not stop taking it without checking with your doctor first. Your doctor may want you to gradually reduce the amount you are using before stopping it completely. This may help prevent a worsening of your condition and reduce the possibility of withdrawal symptoms, such as convulsions, hallucinations, headache, stomach or muscle cramps, tremors, trouble sleeping, or unusual behavior.

This medicine will add to the effects of alcohol and other central nervous system (CNS) depressants. CNS depressants are medicines that slow down the nervous system, which may cause drowsiness or make you less alert. Some examples of CNS depressants are antihistamines or medicine for hay fever, allergies, or colds, sedatives, tranquilizers, or sleeping medicine, prescription pain medicine or narcotics, barbiturates or medicine for seizures, muscle relaxants, or anesthetics (numbing medicines), including some dental anesthetics. This effect may last for a few days after you stop taking this medicine. Check with your doctor before taking any of the above while you are using this medicine.

Do not take other medicines unless they have been discussed with your doctor. This includes prescription or nonprescription (over-the-counter [OTC]) medicines and herbal or vitamin supplements.

Side Effects

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur:

More common

- Drowsiness
- relaxed and calm
- sleepiness

Incidence not known

- Abdominal or stomach pain
- aggressive, angry
- agitation
- attack, assault, or force
- black, tarry stools
- bleeding gums
- blood in the urine or stools
- bluish lips or skin
- blurred vision
- change in consciousness
- chills
- coma
- confusion
- confusion about identity, place, and time
- convulsions
- cough or hoarseness
- dark urine
- decreased urine output
- difficulty with breathing or swallowing
- difficulty with speaking
- discouragement
- dizziness, faintness, or lightheadedness when getting up suddenly from a lying or sitting position
- drooling

- dry mouth
- excitation
- false or unusual sense of well-being
- fast or irregular heartbeat
- feeling sad or empty
- fever with or without chills
- general feeling of tiredness or weakness
- headache
- hives, itching, or rash
- hyperventilation
- increased thirst
- irregular, fast or slow, or shallow breathing
- irritability
- loss of appetite
- loss of balance control
- loss of consciousness
- loss of interest or pleasure
- loss of memory
- lower back or side pain
- muscle pain or cramps
- muscle trembling, jerking, or stiffness
- nausea or vomiting
- not breathing
- painful or difficult urination
- pale or blue lips, fingernails, or skin
- pinpoint red spots on the skin
- problems with memory
- puffiness or swelling of the eyelids or around the eyes, face, lips, or tongue
- reddening of the skin, especially around ears
- restlessness
- seeing, hearing, or feeling things that are not there
- seizures
- shaking
- shuffling walk
- sore throat

- sores, ulcers, or white spots on the lips or in the mouth
- stiffness of the limbs
- sweating
- swelling of the eyes or inside of the nose
- swelling of the face, ankles, or hands
- swollen glands
- thoughts or attempts at killing oneself
- tightness in the chest
- trouble concentrating
- trouble sleeping
- twisting movements of body
- uncontrolled movements, especially of the face, neck, and back
- unexplained bleeding or bruising
- unpleasant breath odor
- unusual bleeding or bruising
- unusual tiredness or weakness
- vomiting of blood
- yellow eyes or skin

Get emergency help immediately if any of the following symptoms of overdose occur:

Symptoms of overdose

- Changes in patterns and rhythms of speech
- increased sweating
- loss of strength or energy
- nightmares
- shakiness and unsteady walk
- slurred speech
- trouble speaking
- unsteadiness, trembling, or other problems with muscle control or coordination
- unusual drowsiness, dullness, tiredness, weakness, or feeling of sluggishness
- unusual excitement, nervousness, restlessness, or irritability
- unusual paleness
- unusual weak feeling

Some side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional

may be able to tell you about ways to prevent or reduce some of these side effects. Check with your health care professional if any of the following side effects continue or are bothersome or if you have any questions about them:

Incidence not known

- Being forgetful
- clumsiness
- constipation
- decreased interest in sexual intercourse
- disturbed color perception
- dizziness or lightheadedness
- double vision
- drowsiness
- feeling of constant movement of self or surroundings
- hair loss or thinning of the hair
- halos around lights
- inability to have or keep an erection
- increased in sexual ability, desire, drive, or performance
- increased interest in sexual intercourse
- lack or loss of self-control
- lethargy
- loss in sexual ability, desire, drive, or performance
- muscle aches, twitching, or weakness
- night blindness
- overbright appearance of lights
- rapid weight gain
- sensation of spinning
- shakiness in the legs, arms, hands, or feet
- shivering
- stupor
- trembling or shaking of the hands or feet
- tunnel vision
- weak or feeble pulse

Other side effects not listed may also occur in some patients. If you notice any other effects, check with your healthcare professional.

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

Portions of this document last updated: Oct. 01, 2019

Original article: <https://www.mayoclinic.org/drugs-supplements/lorazepam-oral-route/side-effects/drg-20072296>

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