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Prosom

Prosom (Oral)

Generic name: estazolam [es-TAZ-oh-lam]

Drug class: Benzodiazepines

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Uses Before taking Dosage Warnings Side effects Brand names



The Prosom brand name has been **discontinued** in the U.S. If generic versions of this product have been approved by the FDA, there may be generic equivalents available.

Oral route(Tablet)

Warning: Risks From Concomitant Use With Opioids; Abuse, Misuse, and Addiction; and Dependence and Withdrawal Reactions

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

Reserve concomitant prescribing of these drugs 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.

The use of benzodiazepines, including estazolam, exposes users to risks of abuse, misuse, and addiction, which can lead to overdose or death. Abuse and misuse of benzodiazepines commonly involve concomitant use of other medications, alcohol, and/or illicit substances, which is associated with an increased frequency of serious adverse outcomes. Before prescribing estazolam and throughout treatment, assess each patient's risk for abuse, misuse, and addiction.

The continued use of benzodiazepines, including estazolam, may lead to clinically significant physical dependence. The risks of dependence and withdrawal increase with longer treatment duration and higher daily dose. Abrupt discontinuation or rapid dosage reduction of estazolam after continued use may precipitate acute withdrawal reactions, which can be life-threatening. To reduce the risk of withdrawal reactions, use a gradual taper to discontinue estazolam or reduce the dosage .

Uses for Prosom

Estazolam is used to treat insomnia (trouble with sleeping). This medicine is for short-term use only, usually 7 to 10 days.

Estazolam is a benzodiazepine. Benzodiazepines belong to the group of medicines called central nervous system (CNS) depressants, which are medicines that slow down the nervous system.

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

Before using Prosom

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 estazolam in the pediatric population. 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 estazolam in the elderly. However, severe drowsiness, dizziness, confusion, clumsiness, or unsteadiness are more likely to occur in the elderly, which may require an adjustment in the dose for patients receiving estazolam.

Breast Feeding

There are no adequate studies in women for determining infant risk when using this medication during breastfeeding. Weigh the potential benefits against the potential risks before taking this medication while breastfeeding.

Interactions with Medicines

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
- Alprazolam

Amobarbital

• Aripiprazole

- Benzhydrocodone
- Bromazepam
- Bromopride
- Buprenorphine
- Butabarbital
- Butalbital
- Butorphanol
- Calcium Oxybate
- Cannabidiol
- Cannabis
- Carbinoxamine
- Carisoprodol
- Cetirizine
- Chloral Hydrate
- Chlorzoxazone
- Clarithromycin
- Clobazam
- Clonazepam
- Cobicistat
- Codeine
- Dantrolene
- Daridorexant
- Dexmedetomidine
- Dihydrocodeine
- Doxylamine
- Esketamine
- Ethchlorvynol
- Fentanyl
- Flibanserin
- Fospropofol
- Gabapentin

- Gabapentin Enacarbil
 Hydrocodone
 Hydromorphone
 Ivacaftor
 Ketamine
 Lacosamide
 Lemborexant
 - Levocetirizine
 - Levorphanol
 - Lofexidine
 - Loxapine
 - Magnesium Oxybate
 - Meclizine
 - Meperidine
 - Mephenesin
 - Mephobarbital
 - Meprobamate
 - Metaxalone
 - Methadone
 - Methocarbamol
 - Methohexital
 - Metoclopramide
 - Midazolam
 - Mirtazapine
 - Morphine
 - Morphine Sulfate Liposome
 - Nalbuphine
 - Olanzapine
 - Oxycodone
 - Oxymorphone
 - Pentazocine
 - Pentobarbital
 - Periciazine
 - Phenobarbital

- Potassium Oxybate
- Pregabalin
- Primidone
- Propofol
- Remimazolam
- Ropeginterferon Alfa-2b-njft
- Scopolamine
- Secobarbital
- Sodium Oxybate
- Sufentanil
- Tapentadol
- Thiopental
- Topiramate
- Tramadol
- Trazodone
- Zolpidem
- Zuranolone

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.

- Rifapentine
- St John's Wort
- Theophylline

Interactions with Food/Tobacco/Alcohol

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 or drug abuse or dependence, or history of, or
- Breathing problems or lung disease, severe or
- Depression, history of—Use with caution. May make these conditions worse.

- · 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 of Prosom

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. If too much of this medicine is taken for a long time, it may become habit-forming (causing mental or physical dependence).

Take estazolam just before going to bed, when you are ready to go to sleep.

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

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 (tablets):
 - · For insomnia:
 - Adults—At first, 1 milligram (mg) at bedtime. Your doctor may adjust your dose if needed.
 - Older adults—At first, 0.5 milligram (mg) at bedtime. Your doctor may adjust your dose if needed.
 - Children—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.

Use this medicine only when you cannot sleep. You do not need to keep a regular dosage schedule for taking it.

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 while using Prosom

It is very important that your doctor check your progress at regular visits to make sure this medicine is working properly. Blood tests may be needed to check for 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 this medicine, tell your doctor right away. Do not breastfeed while you are using this medicine.

Do not take itraconazole (Sporanox®) or ketoconazole (Nizoral®) while you are using this medicine. Taking these medicines together with estazolam may increase the chance of serious side effects.

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 some people, especially older persons, to become drowsy, dizzy, or less alert than they are normally. Even though estazolam is taken at bedtime, it may cause some people to feel drowsy or less alert the next morning. Make sure you know how you react to estazolam before you drive, use machines, or do anything else that could be dangerous if you are dizzy, not alert, or not able to think or see well.

This medicine may cause serious allergic reactions, including anaphylaxis, which can be life-threatening and requires immediate medical attention. Check with your doctor right away if you have a rash, itching, hoarseness, trouble breathing, trouble swallowing, or any swelling of your hands, face, or mouth while you are using this medicine.

Symptoms of an overdose include: change in consciousness, difficult or trouble breathing, difficulty with coordination, irregular, fast or slow, or shallow breathing, loss of consciousness, mood or mental changes, pale or blue lips, fingernails, or skin, sleepiness or unusual drowsiness, or slurred speech. Call your doctor right away if you notice these symptoms.

If you develop any unusual or strange thoughts and behavior while taking estazolam, be sure to discuss it with your doctor. Some changes that have occurred in people taking this medicine are like those seen in people who drink too much alcohol. Other changes might be confusion, worsening of depression, hallucinations (seeing, hearing, or feeling things that are not there), suicidal thoughts, and unusual excitement, nervousness, or irritability.

This medicine may cause sleep-related behaviors including driving a car (sleep-driving), walking (sleep-walking), having sex, making phone calls, or preparing and eating food while you are asleep or not fully awake. If these reactions occur, tell your doctor right away.

This medicine will add to the effects of alcohol and other CNS depressants (medicines that slow down the nervous system, possibly causing drowsiness). Some examples of CNS depressants are antihistamines or medicine for hay fever, other allergies, or colds, sedatives, tranquilizers, or sleeping medicine, prescription pain medicine or narcotics, barbiturates (used 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 stop taking this medicine 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, including hallucinations, seizures, stomach or muscle cramps, tremors, or unusual behavior.

Avoid smoking while you are using this medicine.

If your condition does not improve within 7 to 10 days, or if it becomes worse, check with your doctor.

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 of Prosom

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

- Absence of or decrease in body movement
- · clumsiness or unsteadiness
- dizziness
- · sleepiness or unusual drowsiness

Less common

- · Dry mouth
- false beliefs that cannot be changed by facts
- headache
- · mood or mental changes
- · nausea and vomiting
- poor insight and judgment
- · problems with memory or speech
- tiredness
- trouble thinking and planning
- trouble walking

Rare

- · Aggressive or angry
- · blood in the urine
- bloody nose
- bloody, black, or tarry stools
- burning, crawling, itching, numbness, prickling, "pins and needles", or tingling feelings
- · chest pain or tightness

- chills
- cough
- crying
- · decrease in the amount of urine
- decreased awareness or responsiveness
- decreased reflexes
- · deep or fast breathing with dizziness
- difficult urination
- · dryness or soreness of throat
- dysphoria
- fainting
- false or unusual sense of well-being
- fast, irregular, pounding, or racing heartbeat or pulse
- · fear or nervousness
- · feeling of unreality
- · feeling of warmth
- fever
- frequent strong or increased urge to urinate
- hoarseness
- increased urge to urinate during the night
- irritability
- · lack of feeling or emotion
- loss of bladder control
- loss of memory
- mouth sores or ulcers
- muscle spasm or jerking of all extremities
- · noisy breathing
- numbness of the feet, hands, and around mouth
- paranoia
- problems with memory
- quick to react or overreact emotionally
- rapidly changing moods
- · redness of the face, neck, arms, and occasionally, upper chest
- restlessness

- · seeing, hearing, or feeling things that are not there
- seizures
- sense of detachment from self or body
- severe sleepiness
- · severe stomach pain
- · shakiness and unsteady walk
- · shakiness in the legs, arms, hands, or feet
- skin rash
- sores, ulcers, or white spots on the lips or in the mouth
- · sudden loss of consciousness
- swelling
- · swollen glands
- swollen lymph nodes
- · trouble breathing
- · trouble in swallowing
- · trouble sleeping
- uncaring
- · uncontrolled eye movements
- unsteadiness, trembling, or other problems with muscle control or coordination
- · unusual bleeding or bruising
- · unusual tiredness or weakness
- · voice changes
- · waking to urinate at night

Incidence not known

- Blistering, peeling, or loosening of the skin
- diarrhea
- · fever with or without chills
- · general feeling of tiredness or weakness
- itching
- · joint or muscle pain
- · lower back or side pain
- muscle cramps
- red, irritated eyes

- · red skin lesions, often with a purple center
- sleeplessness
- sweating
- unable to sleep

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

Symptoms of overdose

- · Change in consciousness
- irregular, fast or slow, or shallow breathing
- pale or blue lips, fingernails, or skin
- slurred speech

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:

More common

· Lack or loss of strength

Less common

· Pain in the legs or feet

Rare

- · Blemishes on the skin
- bloated
- blurred vision
- · burning feeling in the chest or stomach
- change in color vision
- change in taste bad unusual or unpleasant (after) taste
- · changes in vision, especially night blindness
- · continuing ringing or buzzing or other unexplained noise in the ears
- cramping in the lower stomach, back, or legs
- · decreased interest in sexual intercourse
- difficulty having a bowel movement (stool)
- · difficulty in moving
- · difficulty seeing at night

- · double vision
- · ear or eye pain
- · excess air or gas in stomach or intestines
- · full feeling
- glare or snowy image caused by bright light
- · hearing loss
- hives or welts
- inability to have or keep an erection
- · increased or decreased appetite
- · increased sensitivity of eyes to sunlight
- indigestion
- loss in sexual ability, desire, drive, or performance
- · muscle pains or stiffness
- · pain in the arms, jaw, or neck
- pain or tenderness around the eyes and cheekbones
- pain, swelling, or redness in joints
- · passing gas
- pimples
- · red, sore eyes
- · redness of the skin
- · seeing double
- sneezing
- · stomach upset or tenderness
- stuffy or runny nose
- · swelling of the breasts
- · weight gain or loss
- · white or brownish vaginal discharge

Incidence not known

- · Increased sensitivity of skin to sunlight
- · redness or other discoloration of skin
- severe sunburn

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.



1 Prosom side effects (more detail)

Related/similar drugs

Ativan

Ativan is a benzodiazepine used to treat anxiety disorders or anxiety associated with depression ...

Reviews & ratings

8.0 / 10

479 Reviews

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Benadryl

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Reviews & ratings

7.0 / 10

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1,504 Reviews

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Reviews & ratings

7.0 / 10

558 Reviews

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Lunesta

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Eszopiclone

Eszopiclone (brand name Lunesta) is a sedative and is used to treat insomnia. Eszopiclone's effects ...

Reviews & ratings

5.7 / 10

442 Reviews

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Temazepam

Temazepam is used to treat insomnia (trouble sleeping). Learn about side effects, interactions and ...

Reviews & ratings

6.5 / 10

448 Reviews

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Melatonin

Melatonin is used to combat jet lag and ease sleep problems like insomnia.

Learn about uses ...

Reviews & ratings

5.7 / 10

239 Reviews

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Diphenhydramine

Diphenhydramine is an antihistamine used to treat sneezing, runny nose, itching, hives and other ...

Reviews & ratings

5.5 / 10

541 Reviews

View more

Commonly used brand name(s)

In the U.S.

• Prosom

Available Dosage Forms:

Tablet

Therapeutic Class: Hypnotic

Pharmacologic Class: Benzodiazepine, Short or Intermediate Acting

More about Prosom (estazolam)

- · Check interactions
- · Compare alternatives
- Reviews (2)
- Drug images
- Latest FDA alerts (2)
- Side effects
- Dosage information
- During pregnancy
- Drug class: benzodiazepines
- Breastfeeding

Professional resources

- Prosom prescribing information
- Estazolam (AHFS Monograph)

Related treatment guides

• Insomnia

Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

Medical Disclaimer

DRUG STATUS

Availability

O Discontinued

Pregnancy & Lactation

& Risk data available

CSA Schedule*

4 Some potential for abuse

Approval History

10+ years

FDA approved 1990

User Reviews & Ratings

Review this drug

Images

Prosom 1 mg (a UC)



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