

TRAMADOL

Pronunciation: TRAM a dol

Brand: ConZip, Ultram, Ultram ER

What is the most important information I should know about tramadol?

- **MISUSE OF THIS MEDICINE CAN CAUSE ADDICTION, OVERDOSE, OR DEATH.** Keep the medication in a place where others cannot get to it.
- Tramadol should not be given to a child younger than 12 years old. **Ultram ER** should not be given to anyone younger than 18 years old.
- **Taking tramadol during pregnancy may cause life-threatening withdrawal symptoms in the newborn.**
- **Fatal side effects can occur if you use tramadol with alcohol, or with other drugs that cause drowsiness or slow your breathing.**

What is tramadol?

- Tramadol is a pain medicine similar to an opioid (sometimes called, a narcotic).
- Tramadol is used to treat moderate to severe pain.
- The **extended-release form** of this medicine is for around-the-clock treatment of pain. This form of tramadol is **not** for use on an as-needed basis for pain.
- Tramadol may also be used for purposes not listed in this medication guide.

What should I discuss with my healthcare provider before taking tramadol?

- You should not take tramadol if you are allergic to it, or if you have:
 - severe asthma or breathing problems
 - a blockage in your stomach or intestines
 - if you have recently used alcohol, sedatives, tranquilizers, or narcotic medications
 - if you have used an MAO inhibitor in the past 14 days (such as isocarboxazid, linezolid, methylene blue injection, phenelzine, rasagiline, selegiline, or tranylcypromine)
- Tramadol should not be given to a child younger than 12 years old. **Ultram ER** should not be given to anyone younger than 18 years old.
- Do not give tramadol to anyone younger than 18 years old who recently had surgery to remove the tonsils or adenoids.
- **Seizures have occurred in some people taking tramadol.** Talk with your doctor about your seizure risk, which may be higher if you have ever had:
 - a head injury, epilepsy or other seizure disorder
 - drug or alcohol addiction
 - a metabolic disorder
- Tell your doctor if you have ever had:
 - breathing problems, sleep apnea
 - liver or kidney disease
 - urination problems
 - problems with your gallbladder, pancreas, or thyroid
 - a stomach disorder
 - mental illness, or suicide attempt
- **If you use tramadol while you are pregnant, your baby could become dependent on the drug.** This can cause life-threatening withdrawal symptoms in the baby after it is born. Babies born dependent on habit-forming medicine may need medical treatment for several weeks.
- **Do not breast-feed.** Tramadol can pass into breast milk and cause drowsiness, breathing problems, or death in a nursing baby.

How should I take tramadol?

- Follow the directions on your prescription label and read all medication guides. **Never use tramadol in larger amounts, or for longer than prescribed.** Tell your doctor if you feel an increased urge to take more of this medicine.
- **Never share this medicine with another person, especially someone with a history of drug abuse or addiction. MISUSE CAN CAUSE ADDICTION, OVERDOSE, OR DEATH.** Keep the medicine in a place where others cannot get to it. Selling or giving away tramadol is against the law.
- Stop taking all other around-the-clock narcotic pain medications when you start taking tramadol.
- Tramadol can be taken with or without food, but take it the same way each time.
- **Swallow the capsule or tablet whole** to avoid exposure to a potentially fatal overdose. Do not crush, chew, break, open, or dissolve.
- **Never crush or break a tramadol pill to inhale the powder or mix it into a liquid to inject the drug into your vein.** This practice has resulted in death.
- **Do not stop using tramadol suddenly,** or you could have unpleasant withdrawal symptoms. Ask your doctor how to safely stop using tramadol.
- Store at room temperature away from moisture and heat. Keep track of your medicine. You should be aware if anyone is using it improperly or without a prescription.

- Do not keep leftover opioid medication. **Just one dose can cause death in someone using this medicine accidentally or improperly.** Ask your pharmacist where to locate a drug take-back disposal program. If there is no take-back program, mix the leftover medicine with cat litter or coffee grounds in a sealed plastic bag throw the bag in the trash.

What happens if I miss a dose?

- Since tramadol is used for pain, you are not likely to miss a dose. Skip any missed dose if it is almost time for your next dose. **Do not** use two doses at one time.

What happens if I overdose?

- Seek emergency medical attention or call the Poison Help line at 1-800-222-1222. **A tramadol overdose can be fatal, especially in a child or other person using the medicine without a prescription.**
- Overdose symptoms may include slow heart rate, severe drowsiness, cold and clammy skin, very slow breathing, or coma.

What should I avoid while taking tramadol?

- **Do not drink alcohol.** Dangerous side effects or death could occur.
- Avoid driving or hazardous activity until you know how this medicine will affect you. Dizziness or drowsiness can cause falls, accidents, or severe injuries.

What are the possible side effects of tramadol?

- Get emergency medical help if you have **signs of an allergic reaction** (hives, difficult breathing, swelling in your face or throat) **or a severe skin reaction** (fever, sore throat, burning in your eyes, skin pain, red or purple skin rash that spreads and causes blistering and peeling).
- **This medicine can slow or stop your breathing, and death may occur.** A person caring for you should seek emergency medical attention if you have slow breathing with long pauses, blue colored lips, or if you are hard to wake up.
- Call your doctor at once if you have:
 - noisy breathing, sighing, shallow breathing,
 - breathing that stops during sleep
 - a slow heart rate or weak pulse
 - a light-headed feeling, like you might pass out
 - seizure (convulsions)
 - **low cortisol levels** --nausea, vomiting, loss of appetite, dizziness, worsening tiredness or weakness.
- **Seek medical attention right away if you have symptoms of serotonin syndrome, such as:** agitation, hallucinations, fever, sweating, shivering, fast heart rate, muscle stiffness, twitching, loss of coordination, nausea, vomiting, or diarrhea.
- **Serious side effects may be more likely in older adults and those who are overweight, malnourished, or debilitated.**
- Long-term use of opioid medication may affect fertility (ability to have children) **in men or women.** It is not known whether opioid effects on fertility are permanent.
- Common side effects may include:
 - constipation, nausea, vomiting, stomach pain
 - dizziness, drowsiness, tiredness
 - headache
 - itching
- This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What other drugs will affect tramadol?

- **You may have breathing problems or withdrawal symptoms if you start or stop taking certain other medicines.** Tell your doctor if you also use an antibiotic, antifungal medication, heart or blood pressure medication, seizure medication, or medicine to treat HIV or hepatitis C.
- **Opioid medication can interact with many other drugs and cause dangerous side effects or death.**
- Be sure your doctor knows if you also use:
 - cold or allergy medicines, bronchodilator asthma/COPD medication, or a diuretic ("water pill")
 - medicines for motion sickness, irritable bowel syndrome, or overactive bladder
 - **other narcotic medications** --opioid pain medicine or prescription cough medicine
 - **a sedative like Valium** --diazepam, alprazolam, lorazepam, Xanax, Klonopin, Versed, and others
 - **drugs that make you sleepy or slow your breathing** --a sleeping pill, muscle relaxer, medicine to treat mood disorders or mental illness
 - **drugs that affect serotonin levels in your body** --a stimulant, or medicine for depression, Parkinson's disease, migraine headaches, serious infections, or nausea and vomiting
- **This list is not complete and many other drugs may affect tramadol.** This includes prescription and over-the-counter medicines, vitamins, and herbal products. Not all possible drug interactions are listed here.

Where can I get more information?

- Your provider or pharmacist can provide more information about tramadol.

Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use this medication only for the indication prescribed.

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