



# Tramadol

**Generic Name:** tramadol (TRAM a dol)

**Brand Names:** *ConZip, Ultram*

## What is tramadol?

Tramadol is a **narcotic-like** pain reliever.

Tramadol is used to treat moderate to **severe pain**.

The **extended-release form** of tramadol is for around-the-clock treatment of pain. This form of tramadol is **not** for use on an as-needed basis for pain.

## Important information

You should not take tramadol if you have severe breathing problems, a blockage in your stomach or intestines, or if you have recently used alcohol, sedatives, tranquilizers, narcotic medication, or an MAO inhibitor (isocarboxazid, linezolid, methylene blue injection, phenelzine, rasagiline, selegiline, tranylcypromine, and others).

Tramadol can slow or stop your breathing, and may be habit-forming. **MISUSE OF THIS MEDICINE CAN CAUSE ADDICTION, OVERDOSE, OR DEATH, especially in a child or other person using the medicine without a prescription.**

This medicine is not for use in children 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.**

Seizures (convulsions) have occurred in some people taking this medicine. Tramadol may be more likely to cause a seizure if you have a history of seizures or head injury, a metabolic disorder, or if you are taking certain medicines such as antidepressants, muscle relaxers, narcotic, or medicine for nausea and vomiting.

**Tramadol can interact with many other drugs and cause dangerous side effects or death.** Tell your doctor about all your current medicines and any you start or stop using.

Do not crush the tramadol tablet. This medicine is for oral (by mouth) use only. Powder from a crushed tablet should not be inhaled or diluted with liquid and injected into the body. Using this medicine by inhalation or injection can cause life-threatening side effects, overdose, or death.

## Before taking this medicine

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; or
- 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; or
- if you also use certain antibiotics, antifungal medications, heart or blood pressure medications, or medicines to treat HIV or AIDS.

**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. Tell your doctor if you are pregnant or plan to become pregnant.

**Do not breast-feed while taking tramadol.** This medicine can pass into breast milk and cause drowsiness, breathing problems, or death in a nursing baby.

To make sure tramadol is safe for you, tell your doctor if you have ever had:

- liver or kidney disease;
- a stomach disorder;
- mental illness, or suicide attempt; or
- if you use a sedative like Valium (diazepam, alprazolam, lorazepam, Ativan, Klonopin, Restoril, Tranxene, Versed, Xanax, and others).

## How should I take tramadol?

Take tramadol exactly as prescribed. Follow all directions on your prescription label. Tramadol can slow or stop your breathing, especially when you start using this medicine or whenever your dose is changed. Never take tramadol in larger amounts, or for longer than prescribed. Tell your doctor if the medicine seems to stop working as well in relieving your pain.

Tramadol may be habit-forming, even at regular doses. Never share this medicine with another person, especially someone with a history of drug abuse or addiction. **MISUSE OF PAIN MEDICATION CAN CAUSE ADDICTION, OVERDOSE, OR DEATH, especially in a child or other person using the medicine without a prescription.** Selling or giving away this medicine 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.

Do not crush, break, or open an extended-release tablet or capsule (**ConZip, Ultram ER**). Swallow it whole to avoid exposure to a potentially fatal dose.

**Never crush or break a tramadol tablet to inhale the powder or mix it into a liquid to inject the drug into your vein.** This practice has resulted in death.

If you use the extended-release tablet, the tablet shell may pass into your stools (bowel movements). This is normal and does not mean that you are not receiving enough of the medicine.

Do not stop using tramadol suddenly, or you could have unpleasant withdrawal symptoms. Ask your doctor how to safely stop using this medicine.

Store at room temperature away from moisture and heat.

Keep track of the amount of medicine used from each new bottle. Tramadol is a drug of abuse and you should be aware if anyone is using your medicine improperly or without a prescription.

See also: **Dosage Information** (in more detail)

## 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 scheduled dose. Do not take extra medicine to make up the missed dose.

## 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 breathing and heart rate, severe drowsiness, cold and clammy skin, and fainting.

## What should I avoid while taking tramadol?

**Do not drink alcohol.** Dangerous side effects or death could occur.

Tramadol may impair your thinking or reactions. Avoid driving or operating machinery until you know how this medicine will affect you. Dizziness or severe drowsiness can cause falls or other accidents.

## Tramadol side effects

Get emergency medical help if you have **signs of an allergic reaction to tramadol**: hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

Like other narcotic medicines, tramadol can slow your breathing. Death may occur if breathing becomes too weak.

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;
- a slow heart rate or weak pulse;
- a light-headed feeling, like you might pass out;
- seizure (convulsions);
- infertility, missed menstrual periods;
- impotence, sexual problems, loss of interest in sex;
- **low cortisol levels** - nausea, vomiting, loss of appetite, dizziness, worsening tiredness or weakness; or
- **severe skin reaction** - fever, sore throat, swelling in your face or tongue, burning in your eyes, skin pain, followed by a red or purple skin rash that spreads (especially in the face or upper body) and causes blistering and peeling.

**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 tramadol side effects may include:

- headache, dizziness, drowsiness, tired feeling;
- constipation, diarrhea, nausea, vomiting, stomach pain;
- feeling nervous or anxious; or
- itching, sweating, flushing (warmth, redness, or tingly feeling).

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.

**See also: Side effects (in more detail)**

## Tramadol dosing information

### Usual Adult Dose for Pain:

Immediate-release: 50 to 100 mg orally every 4 to 6 hours as needed for pain

Maximum dose: 400 mg per day

#### Comments:

-Dose should be individualized; for patients not requiring rapid onset of analgesic effect, the tolerability may be increased by initiating at the lowest possible dose and titrating upward.

Use: For the management of moderate to moderately severe pain.

### Usual Adult Dose for Chronic Pain:

For patients with moderate to moderately severe chronic pain not requiring rapid onset of analgesic effect, tolerability can be improved by initiating slowly

#### Immediate-Release (IR):

-Initial dose: 25 mg orally once a day; titrate in 25 mg increments every 3 days to reach a dose of 25 mg four times a day; thereafter increase by 50 mg as tolerated every 3 days to reach a dose of 50 mg four times a day

-Maintenance dose: After titration, 50 to 100 mg orally as needed for pain every 4 to 6 hours

-Maximum dose: 400 mg per day

#### Extended-Release (ER):

-Initial dose (tramadol-naïve): 100 mg orally once a day

-Individually titrate in 100 mg increments every 5 days to an effective dose that minimizes adverse reactions

-Maximum Dose: 300 mg orally per day

Initial Dose for patients CURRENTLY receiving IR tramadol: Calculate 24-hour IR requirement and initiate with a total daily ER dose rounded down to the next lowest 100 mg increment orally once a day

Initial Dose for those on Other Opioids: Discontinue all other around the clock opioid drugs; initiate with ER 100 mg orally once a day

-Individually titrate in 100 mg increments every 5 days to an effective dose that minimizes adverse reactions

-Maximum Dose: 300 mg per day

#### Comments:

-Due to limitations of dose selection with ER formulations, some patients may not be able to convert from the IR to ER.

-The ER products should not be used with other tramadol products and should not be taken more often than once a day.

-Monitor patients closely for respiratory depression, especially within the first 24 to 72 hours of therapy and following dose increases.

Use: For the management of moderate to moderately severe chronic pain in adults who require around-the-clock treatment of their pain for an extended period of time.

### Usual Geriatric Dose for Pain:

Age: 75 years or older: Maximum dose: 300 mg per day

#### Comments:

-Respiratory depression is the chief risk for elderly patients treated with opioids; titrate dose slowly and monitor closely for signs of central nervous system and respiratory depression.

### Usual Geriatric Dose for Chronic Pain:

Age: 75 years or older: Maximum dose: 300 mg per day

Comments:

-Respiratory depression is the chief risk for elderly patients treated with opioids; titrate dose slowly and monitor closely for signs of central nervous system and respiratory depression.

**Usual Pediatric Dose for Pain:**

17 years or older:

Immediate-release: 50 to 100 mg orally every 4 to 6 hours as needed for pain

Maximum dose: 400 mg per day

For patients with moderate to moderately severe chronic pain not requiring rapid onset of analgesic effect, tolerability can be improved by initiating slowly:

Immediate-Release:

-Initial dose: 25 mg orally once daily; titrate in 25 mg increments every 3 days to reach a dose of 25 mg four times a day; thereafter increase by 50 mg as tolerated every 3 days to reach a dose of 50 mg four times a day

-Maintenance dose: After titration, 50 to 100 mg orally as needed for pain every 4 to 6 hours

-Maximum dose: 400 mg per day

Comments:

-Dose should be individualized; starting at the lowest possible dose and titrating upward may result in increased tolerability and fewer drug discontinuations.

Use: For the management of moderate to moderately severe pain.

## What other drugs will affect tramadol?

**Narcotic (opioid) medication can interact with many other drugs and cause dangerous side effects or death.** Be sure your doctor knows if you also use:

- **other narcotic medications** - opioid pain medicine or prescription cough medicine;
- **drugs that make you sleepy or slow your breathing** - a sleeping pill, muscle relaxer, sedative, tranquilizer, or antipsychotic medicine; or
- **drugs that affect serotonin levels in your body** - medicine for depression, Parkinson's disease, migraine headaches, serious infections, or prevention of nausea and vomiting.

This list is not complete. Other drugs may interact with tramadol, including prescription and over-the-counter medicines, vitamins, and herbal products. Not all possible interactions are listed in this medication guide.

## Where can I get more information?

- Your 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 tramadol only for the indication prescribed.
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