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Tramadol



Generic Name: tramadol (TRAM a dol)

Brand Names: *ConZip, Ultram*

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Overview

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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.

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Tramadol may also be used for purposes not listed in this medication guide.

Important information

You should not take tramadol if you have used alcohol, sedatives, tranquilizers, or narcotic medications within the past few hours.

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. Do not crush, break, or open an extended-release pill. Swallow it whole to avoid exposure to a potentially fatal dose.

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 may be habit-forming, even at regular doses.

Take this medicine exactly as prescribed by your doctor. Never share the medicine with another person. MISUSE OF NARCOTIC PAIN MEDICATION CAN CAUSE ADDICTION, OVERDOSE, OR DEATH, especially in a child or other person using the medicine without a prescription.

Tell your doctor if you are [pregnant](#) . **Tramadol may cause life-threatening withdrawal symptoms in a newborn.**

Do not drink alcohol. Dangerous side effects or death can occur when alcohol is combined with tramadol.

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:



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- severe asthma or breathing problems;
- a blockage in your stomach or intestines;
- if you have recently used alcohol, sedatives, tranquilizers, or narcotic medications.

Seizures have occurred in some people taking tramadol. Talk with your doctor about your seizure [risk](#), which may be higher if you have:

- a history of head injury, epilepsy or other seizure disorder;
- a history of drug or alcohol addiction;
- a metabolic disorder; or
- if you are also using certain medicines to treat migraine headaches, muscle spasms, depression, mental [illness](#), or nausea and vomiting.

Some medicines can interact with tramadol and cause a serious condition called **serotonin syndrome**. Be sure your doctor knows if you also take medicine for depression, mental illness, Parkinson's disease, migraine headaches, serious infections, or prevention of nausea and vomiting. Ask your doctor before making any changes in how or when you take your medications.

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

- liver or kidney disease;
- a stomach disorder; or
- a history of drug abuse, alcohol addiction, mental illness, or suicide attempt.

Tramadol is more likely to cause breathing problems in older adults and people who are severely ill, malnourished, or otherwise debilitated.

Tramadol may be habit forming and should be used only by the person it was prescribed for. **Never share this medicine with another person, especially someone with a history of drug abuse or addiction.** Keep the medication in a place where others cannot get to it. Selling or giving away tramadol to any other person is against the law.

It is not known whether tramadol will harm an unborn baby. If you use this medicine 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.

Tramadol can pass into breast milk and may harm a nursing baby. You should not breast-feed while you are taking this medicine.

Do not give this medication to anyone younger than 16 years old without the advice of a doctor. **Ultram ER** should not be given to anyone younger than 18 years old.

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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 in larger amounts, or for longer than prescribed. Tell your doctor if the medicine seems to stop working as well in relieving your pain.

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 pill to inhale the powder or mix it into a liquid to inject the drug into your vein. This practice has resulted in death with the misuse of tramadol and similar prescription drugs.

If you use the tramadol 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?

Do not drink alcohol. Dangerous side effects or death can occur when alcohol is combined with tramadol. Check your food and medicine labels to be sure these products do not contain alcohol.

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.

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Tramadol side effects

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

Tramadol is not for use in children. Seek emergency medical attention if a child has taken this medicine and has: noisy breathing, sighing, slow breathing with long pauses between breaths; being unusually sleepy or hard to wake up; blue colored lips.

Call your doctor at once if you have:

- seizure (convulsions);
- weak or shallow breathing;
- infertility, missed menstrual periods;
- impotence, sexual problems, loss of interest in sex; or
- 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.

Common tramadol side effects may include:

- headache, dizziness, drowsiness, tired feeling;
- constipation, diarrhea, nausea, vomiting, stomach pain; or
- feeling nervous or anxious.
- 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:

For mild to moderate severe chronic pain not requiring rapid onset of analgesic effect:

Initial dose: 25 mg every morning

Titration: increase in 25 mg increments as separate doses every 3 days to reach 100 mg per day taken as 25 mg 4 times per day. Then the total daily dose may be increased by 50 mg as tolerated every 3 days to reach 200 mg per day taken as 50 mg 4 times per day.

Maintenance: After titration, tramadol 50 mg to 100 mg can be administered as needed for pain relief every 4 to 6 hours not to exceed 400 mg per day.

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:

Extended-Release Tablets:

Initial Dose: 100 mg once daily and titrated up as necessary by 100 mg increments every five days to relief of pain and depending upon tolerability.

Maximum Dose: Extended-release tablets should not be administered at a dose exceeding 300 mg per day.

For patients in whom rapid onset of analgesic effect is required and for whom the benefits outweigh the risk of discontinuation due to adverse events associated with higher initial dose:

Dose: 50 mg to 100 mg can be administered as needed for pain relief every 4 to 6 hours, not to exceed 400 mg per day.

Tramadol Extended-Release (ER):

Patients not currently treated with tramadol immediate-release (IR):

Initial dose: 100 mg once daily and titrated up as necessary by 100 mg increments every 5 days to relief of pain and individualized according to patient need and tolerability.

Maximum dose: 300 mg per day

Patients currently on tramadol IR (immediate release) :

Calculate the 24-hour tramadol IR dose:

Initial dose: Round down to the next lowest 100 mg increment. The dose may subsequently be individualized according to patient need and tolerability.

Maximum dose: 300 mg per day

Due to limitations in flexibility of dose selection with tramadol ER, some patients maintained

on immediate release products may not be able to convert.

Usual Geriatric Dose for Pain:

For patients over 65 years:

Dose selection should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or other drug therapy.

For patients over 75 years:

Maximum dose of regular oral tablets: 300 mg per day in divided doses

Usual Pediatric Dose for Pain:

4 to 16 years:

Immediate release formulations: 1 to 2 mg/kg/dose every 4 to 6 hours

Maximum single dose: 100 mg

Maximum total daily dose is the lesser of: 8 mg/kg/day or 400 mg/day

16 years and older:

Initial dose: 50 to 100 mg every 4 to 6 hours

Maximum dose: 400 mg/day

Alternatively, for patients not requiring a rapid onset of effect, side effects may be decreased by initiating dosage at 25 mg/day and increasing by 25 mg every 3 days up to 25 mg 4 times a day. Dosage may then be increased by 50 mg every 3 days as tolerated to 50 mg 4 times a day.

16 years and older:

Oral disintegrating tablet (ODT):

Initial: 50 to 100 mg every 4 to 6 hours

Maximum: 400 mg/day

Alternatively, for patients not requiring a rapid onset of effect, side effects may be decreased by initiating dosage at 50 mg/day and increasing by 50 mg every 3 days up to 50 mg 4 times a day.

Maximum: 400 mg/day

16 years and older:

Extended-release formulations:

Initial: 100 mg once daily

Titrate by 100 mg increments every 2 to 3 days if needed for pain control

Maximum: 300 mg/day

What other drugs will affect tramadol?

Some medicines can cause unwanted or dangerous effects when used with tramadol. Tell each of your healthcare providers about all medicines you use now, and any medicine you start or stop using.

Taking this medicine with other drugs that make you sleepy or slow your breathing can cause dangerous or life-threatening side effects. Ask your doctor before taking tramadol with a sleeping pill, narcotic pain medicine, muscle relaxer, or medicine for anxiety, depression, or seizures.

Many drugs can interact with tramadol, including prescription and over-the-counter medicines, vitamins,

and herbal products. Not all possible interactions are listed here. Tell each of your health care providers about all medicines you use now and any medicine you start or stop using.

Next → [Side Effects](#)



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Where can I get more information?

- Your pharmacist can provide more information.

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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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DRUG STATUS



Availability
Prescription only



Pregnancy Category





Risk cannot be ruled out



CSA Schedule
Some potential for abuse



Approval History
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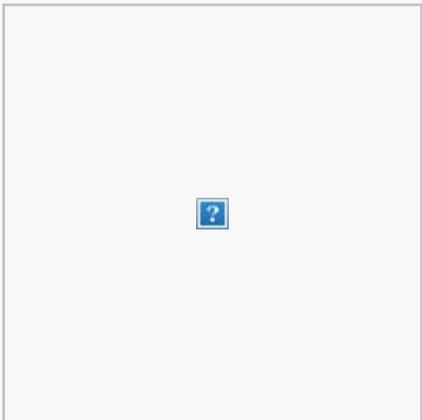
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