

Medication Guide

Tramadol Hydrochloride Tablets (TRAM-a-dol HYE-droe-KLOR-ide), CIV

Tramadol tablets are:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used for the management pain in adults, when other pain treatments such as non-opioid pain medicines do not treat your pain well enough or you cannot tolerate them.
- An opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death.

Important information about tramadol tablets:

- **Get emergency help or call 911 right away if you take too much tramadol tablets (overdose).** When your first start taking tramadol, when your dose is changed, or if you take too much (overdose), serious or life-threatening breathing problems that can lead to death may occur. Talk to your healthcare provider about naloxone, a medicine for the emergency treatment of an opioid overdose.
- Taking tramadol tablets with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.
- Never give anyone else your tramadol tablets. They could die from taking it. Selling or giving away tramadol tablets is against the law.
- Store tramadol tablets securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.

Important Information Guiding Use in Pediatric Patients:

- Do not give tramadol tablets to a child younger than 12 years of age.
 - Do not give tramadol tablets to a child younger than 18 years of age after surgery to remove the tonsils and/or adenoids.
 - Avoid giving tramadol tablets to children between 12 to 18 years of age who have risk factors for breathing problems such as obstructive sleep apnea, obesity, or underlying lung problems.
- Do not take tramadol tablets if you have:
- Severe asthma, trouble breathing, or other lung problems.
 - A bowel blockage or have narrowing of the stomach or intestines.
 - An allergy to tramadol.
 - Taken a Monoamine Oxidase Inhibitor, MAOI, (medicine used for depression) within the last 14 days.

- Before taking tramadol tablets, tell your healthcare provider if you have a history of:
 - head injury, seizures
 - liver, kidney, thyroid problems
 - problems urinating
 - pancreas or gallbladder problems
 - abuse of street or prescription drugs, alcohol addiction, opioid overdose, or mental health problems.

Tell your healthcare provider if you are:

- **pregnant or planning to become pregnant.** Prolonged use of tramadol tablets during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
- **breastfeeding.** Not recommended; It may harm your baby.
- living in a household where there are small children or someone who has

abused street or prescription drugs.

- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking tramadol tablets with certain other medicines can cause serious side effects that could lead to death.

When taking tramadol tablets:

- Do not change your dose. Take tramadol tablets exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed.
- Take your prescribed dose as indicated by your healthcare provider. The maximum dosage is 1 or 2 tablets every 4 to 6 hours, as needed for pain relief. Do not take more than your prescribed dose and do not take more than 8 tablets per day. If you miss a dose, take your next dose at your usual time.
- Call your healthcare provider if the dose you are taking does not control your pain.
- If you have been taking tramadol tablets regularly, do not stop taking tramadol tablets without talking to your healthcare provider.
- Dispose of expired, unwanted, or unused tramadol tablets by taking your drug to an authorized Drug Enforcement Administration (DEA)-registered collector or drug take-back program. If one is not available, you can dispose of tramadol tablets by mixing the product with dirt, cat litter, or coffee grounds; placing the mixture in a sealed plastic bag, and throwing the bag in your trash.

While taking tramadol tablets DO NOT:

- Drive or operate heavy machinery, until you know how tramadol tablets affects you. Tramadol tablets can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or

over-the-counter medicines that contain alcohol. Using products containing alcohol during treatment with tramadol tablets may cause you to overdose and die.

The possible side effects of tramadol tablets:

- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain. Call your healthcare provider if you have any of these symptoms and they are severe.

Get emergency medical help or call 911 if you have:

- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue, or throat, extreme drowsiness, light-headedness when changing positions, feeling faint, agitation, high body temperature, trouble walking, stiff muscles, or mental changes such as confusion.
- These are not all the possible side effects of tramadol tablets. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. For more information go to dailymed.nlm.nih.gov or call 1-888-943-3210 or 1-855-926-3384

MACLEODS

Manufactured for :

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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