

Medication Guide available at
<https://www.sunpharma.com/usa/products>

Medication Guide
Tramadol Hydrochloride (tram a dol hye'' droe cklo' ride)
and Acetaminophen (a seet'' a min' oh fen)
Tablets, CIV

Tramadol hydrochloride and acetaminophen tablets are:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used for the short-term (five days or less) management of acute pain, 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 hydrochloride and acetaminophen tablets:

- **Get emergency help or call 911 right away if you take too much tramadol hydrochloride and acetaminophen tablets (overdose).** When you first start taking tramadol hydrochloride and acetaminophen tablets, 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.
- Tramadol hydrochloride and acetaminophen tablets can cause severe drowsiness, breathing problems (respiratory depression), coma and death when taken with benzodiazepines or other medicines that depress consciousness.
- Never give anyone else your tramadol hydrochloride and acetaminophen tablets. They could die from taking it. Selling or giving away tramadol hydrochloride and acetaminophen tablets are against the law.
- Store tramadol hydrochloride and acetaminophen tablets securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.
- Get emergency help right away if you take more than 4,000 mg of acetaminophen in 1 day. Taking tramadol hydrochloride and acetaminophen tablets with other products that contain acetaminophen can lead to serious liver problems and death.

Important information guiding use in pediatric patients:

- Do not give tramadol hydrochloride and acetaminophen tablets to a child younger than 12 years of age.
- Do not give tramadol hydrochloride and acetaminophen tablets to a child younger than 18 years of age after surgery to remove the tonsils and/or adenoids.
- Avoid giving tramadol hydrochloride and acetaminophen 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 hydrochloride and acetaminophen 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 any of its ingredients (e.g., tramadol hydrochloride or acetaminophen).
- Taken a Monoamine Oxidase Inhibitor, MAOI, (medicine used for depression) within the last 14 days.

Before taking tramadol hydrochloride and acetaminophen 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:

- noticing your pain getting worse. If your pain gets worse after you take tramadol hydrochloride and acetaminophen tablets, do not take more of tramadol hydrochloride and acetaminophen tablets without first talking to your healthcare provider. Talk to your healthcare provider if the pain that you have increases, if you feel more sensitive to pain, or if you have new pain after taking tramadol hydrochloride and acetaminophen tablets.
- **pregnant or planning to become pregnant.** Use of tramadol hydrochloride and acetaminophen tablets for an extended period of time 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 hydrochloride and acetaminophen tablets with certain other medicines can cause serious side effects that could lead to death.
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When taking tramadol hydrochloride and acetaminophen tablets:

- Do not change your dose. Take tramadol hydrochloride and acetaminophen tablets exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed.
- For acute (short-term) pain, you may only need to take tramadol hydrochloride and acetaminophen tablets for a few days. You may have some tramadol hydrochloride and acetaminophen tablets left over that you did not use. See disposal information at the bottom of this section for directions on how to safely throw away (dispose of) your unused tramadol hydrochloride and acetaminophen tablets.
- Take your prescribed dose: 2 tablets every 4 to 6 hours as needed for pain relief for a maximum of 5 days. 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 hydrochloride and acetaminophen tablets regularly, do not stop taking tramadol hydrochloride and acetaminophen tablets without talking to your healthcare provider.
- Dispose of expired, unwanted, or unused tramadol hydrochloride and acetaminophen 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 hydrochloride and acetaminophen 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. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

While taking tramadol hydrochloride and acetaminophen tablets DO NOT:

- Drive or operate heavy machinery, until you know how tramadol hydrochloride and acetaminophen tablets affect you. Tramadol hydrochloride and acetaminophen 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 hydrochloride and acetaminophen tablets may cause you to overdose and die.

The possible side effects of tramadol hydrochloride and acetaminophen tablets are:

- 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 right away 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 hydrochloride and acetaminophen tablets. Call your healthcare provider 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**

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