Medication Guide

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Tramadol Hydrochloride (TRAM a dol Hye" droe klor' ide) Tablets, CIV

Tramadol hydrochloride 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 hydrochloride tablets:

- **Get emergency help right away if you take too many tramadol hydrochloride tablets (overdose).** When you first start taking tramadol hydrochloride tablets, when your dose is changed, or if you take too many (overdose), serious or life-threatening breathing problems that can lead to death may occur.
- Taking tramadol hydrochloride 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 hydrochloride tablets. They could die from taking them. Store tramadol hydrochloride tablets away from children and in a safe place to prevent stealing or abuse. Selling or giving away tramadol hydrochloride tablets is against the law.

Important Information Guiding Use in Pediatric Patients:

- Do not give tramadol hydrochloride tablets to a child younger than 12 years of age.
- Do not give tramadol hydrochloride tablets to a child younger than 18 years of age after surgery to remove the tonsils and/or adenoids.
- Avoid giving tramadol hydrochloride 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 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 hydrochloride tablets, tell your healthcare provider if you have a history of:
Tell your healthcare provider if you are:

- **pregnant or planning to become pregnant.** Prolonged use of tramadol hydrochloride 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.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking tramadol hydrochloride tablets with certain other medicines can cause serious side effects that could lead to death.

When taking tramadol hydrochloride tablets:

- Do not change your dose. Take tramadol hydrochloride 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 hydrochloride tablets regularly, do not stop taking tramadol hydrochloride tablets without talking to your healthcare provider.
- After you stop taking tramadol hydrochloride tablets, ask your pharmacist how to dispose of any unused tablets.

While taking tramadol hydrochloride tablets DO NOT:

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

The possible side effects of tramadol hydrochloride 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 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 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**

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This Medication Guide has been approved by the U.S. Food and Drug Administration. Rev. A 9/2017