

MEDICATION GUIDE
Tramadol Hydrochloride Extended-Release
Tablets, CIV
(tram' a dol hye" droe klor' ide)

Tramadol hydrochloride extended-release tablets are:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage severe and persistent pain that requires an extended treatment period with a daily opioid pain medicine, when other pain medicines do not treat your pain well enough or you cannot tolerate them.
- A long-acting (extended-release) 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.
- Not to be taken on an "as needed" basis.

Important information about tramadol hydrochloride extended-release tablets:

- **Get emergency help or call 911 right away if you take too much tramadol hydrochloride extended-release tablets (overdose).** When you first start taking tramadol hydrochloride extended-release 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. Ask your healthcare provider about medicines like naloxone or nalmefene that can be used in an emergency to reverse an opioid overdose.
- Taking tramadol hydrochloride extended-release tablets with other opioid medicines, benzodiazepines, gabapentinoids (gabapentin or pregabalin), 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 extended-release tablets. They could die from taking it. Selling or giving away tramadol hydrochloride extended-release tablets is against the law.
- Store tramadol hydrochloride extended-release 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 hydrochloride extended-release tablets to a child younger than 12 years of age.
- Do not give tramadol hydrochloride extended-release tablets to a child younger than 18 years of age after surgery to remove the tonsils and/or adenoids.
- Avoid giving tramadol hydrochloride extended-release 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 extended-release tablets if you have:

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.

Before taking tramadol hydrochloride extended-release tablets, tell your healthcare provider if you have a history of:

- head injury, seizures
- problems urinating
- abuse of street or prescription drugs, alcohol addiction, opioid overdose, or mental health problems.
- liver, kidney, thyroid problems
- pancreas or gallbladder problems

Tell your healthcare provider if you are:

- noticing your pain getting worse. If your pain gets worse after you take tramadol hydrochloride extended-release tablets, do not take more of tramadol hydrochloride extended-release 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 extended-release tablets.
- Are pregnant or planning to become pregnant. Use of tramadol hydrochloride extended-release 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 during treatment with tramadol hydrochloride extended-release tablets; 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 extended-release tablets with certain other medicines can cause serious side effects that could lead to death.

When taking tramadol hydrochloride extended-release tablets:

- Do not change your dose. Take tramadol hydrochloride extended-release tablets exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed.
- Take your prescribed dose once a day at the same time every day. Do not take more than your prescribed dose. If you miss a dose, take your next dose at your usual time.
- Swallow tramadol hydrochloride extended-release tablets whole. Do not cut, break, chew, crush, dissolve, snort, or inject tramadol hydrochloride extended-release tablets because this may cause you to overdose and die.
- **Call your healthcare provider if the dose you are taking does not control your pain.**
- **Do not stop taking tramadol hydrochloride extended-release tablets without talking to your healthcare provider.**
- Dispose of expired, unwanted, or unused tramadol hydrochloride extended-release tablets by taking your drug to an authorized DEA-registered collector or drug take-back program. If one is not available, you can dispose of tramadol hydrochloride extended-release 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 extended-release tablets DO NOT:

- Drive or operate heavy machinery, until you know how tramadol hydrochloride extended-release tablet affects you. Tramadol hydrochloride extended-

release 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 extended-release tablets may cause you to overdose and die.

The possible side effects of tramadol hydrochloride extended-release tablets:

- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain, seizure. 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 extended-release 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 call Macleods Pharma USA, Inc. at 1-888-943-3210 or 1-855-926-3384.

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

MACLEODS


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