ULTRAM- tramadol hcl 100mg tablet, extended release
Advanced Rx Pharmacy of Tennessee, LLC

Tramadol HCl ER 100mg tablets #60

Medication Guide

MEDICATION GUIDE

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 pain severe enough to require daily around-the-clock, long-term treatment with an opioid, when other pain treatments such as non-opioid pain medicines or immediate-release opioid 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 for use to treat pain that is not around-the-clock.

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. Talk to your healthcare provider about naloxone, a medicine for the emergency treatment of an opioid overdose.
Taking tramadol hydrochloride extended-release 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 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:

pregnant or planning to become pregnant . Prolonged use of tramadol hydrochloride extended-release 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 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.

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 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 www.lupinpharmaceuticals.com or call Lupin Pharmaceuticals, Inc. at 1-800-399-2561.

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

Manufactured for:

Lupin Pharmaceuticals, Inc.

Baltimore, Maryland 21202

United States

Manufactured by:

Lupin Limited

Pithampur (M.P.) - 454 775

INDIA

Revised: August 23, 2020 ID#: 266045

Dosage and Administration Section

2 DOSAGE AND ADMINISTRATION

2.1 Important Dosage and Administration Instructions

Tramadol hydrochloride extended-release tablets should be prescribed only by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain.

Do not use tramadol hydrochloride extended-release tablets concomitantly with other tramadol products [see Warnings and Precautions (5.6), (5.14)] .
Do not administer tramadol hydrochloride extended-release tablets at a dose exceeding 300 mg per day.
Use the lowest effective dosage for the shortest duration consistent with individual patient treatment goals [see Warnings and Precautions (5.7)] .
Initiate the dosing regimen for each patient individually, taking into account the patient's severity of pain, patient response, prior analgesic treatment experience, and risk factors for addiction, abuse, and misuse [see Warnings and Precautions (5.1)]
Monitor patients closely for respiratory depression, especially within the first 24 to 72 hours of initiating therapy and following dosage increases with tramadol hydrochloride extended-release tablets and adjust the dosage accordingly [see Warnings and Precautions (5.3)] .
Instruct patients to swallow tramadol hydrochloride extended-release tablets whole [see Patient Counseling Information (17)] , and to take it with liquid. Crushing, chewing, splitting, or dissolving tramadol hydrochloride extended-release tablets will result in uncontrolled delivery of tramadol and can lead to overdose or death [see Warnings and Precautions (5.1)] .
Tramadol hydrochloride extended-release tablets may be taken without regard to food, It is recommended that tramadol hydrochloride extended-release tablets be taken in a consistent manner [see Clinical Pharmacology (12.3)] .

2.2 Patient Access to Naloxone for the Emergency Treatment of Opioid Overdose

Discuss the availability of naloxone for the emergency treatment of opioid overdose with the patient and caregiver and assess the potential need for access to naloxone, both when initiating and renewing treatment with tramadol hydrochloride extended release tablets [see Warnings and Precautions (5.3), Patient Counseling Information (17)].

Inform patients and caregivers about the various ways to obtain naloxone as permitted by individual state naloxone dispensing and prescribing requirements or guidelines (e.g., by prescription, directly from a pharmacist, or as part of a community-based program).

Consider prescribing naloxone, based on the patient's risk factors for overdose, such as concomitant use of CNS depressants, a history of opioid use disorder, or prior opioid overdose. The presence of risk factors for overdose should not prevent the proper management of pain in any given patient [see

Warnings and Precautions (5.1, 5.3, 5.7)].

Consider prescribing naloxone if the patient has household members (including children) or other close contacts at risk for accidental ingestion or overdose.

2.3 Initial Dosage

Patients Not Currently on a Tramadol Product

The initial dose of tramadol hydrochloride extended-release tablets is 100 mg once daily.

Patients Currently on Tramadol Immediate-Release (IR) Products

Calculate the 24-hour tramadol IR dose and initiate a total daily dose of tramadol hydrochloride extended-release tablets rounded down to the next lower 100 mg increment. The dose may subsequently be individualized according to patient need.

Due to limitations in flexibility of dose selection with tramadol hydrochloride extended-release tablets, some patients maintained on tramadol IR products may not be able to convert to tramadol hydrochloride extended-release tablets.

Conversion from Other Opioids to Tramadol Hydrochloride Extended-Release Tablets

Discontinue all other around-the-clock opioid drugs when tramadol hydrochloride extended-release tablets therapy is initiated. There are no established conversion ratios for conversion from other opioids to tramadol hydrochloride extended-release tablets defined by clinical trials. Initiate dosing using tramadol hydrochloride extended-release tablets 100 mg once a day.

2.4 Titration and Maintenance of Therapy

Individually titrate tramadol hydrochloride extended-release tablets by 100 mg every five days to a dose that provides adequate analgesia and minimizes adverse reactions. The maximum daily dose of tramadol hydrochloride extended-release tablets is 300 mg per day.

Continually reevaluate patients receiving tramadol hydrochloride extended-release tablets to assess the maintenance of pain control and the relative incidence of adverse reactions, as well as monitoring for the development of addiction, abuse, or misuse [see Warnings and Precautions (5.1)]. Frequent communication is important among the prescriber, other members of the healthcare team, the patient, and the caregiver/family during periods of changing analgesic requirements, including initial titration. During chronic therapy, periodically reassess the continued need for the use of opioid analgesics.

Patients who experience breakthrough pain may require a dosage adjustment of tramadol hydrochloride extended-release tablets, or may need rescue medication with an appropriate dose of an immediate-release analgesic. If the level of pain increases after dosage stabilization, attempt to identify the source of increased pain before increasing the tramadol hydrochloride extended-release tablets dosage.

If unacceptable opioid-related adverse reactions are observed, consider reducing the dosage. Adjust the dosage to obtain an appropriate balance between management of pain and opioid-related adverse reactions.

2.5 Safe Reduction or Discontinuation OfTramadol Hydrochloride Extended-Release Tablets

Do not abruptly discontinue tramadol hydrochloride extended-release tablets in patients who may be physically dependent on opioids. Rapid discontinuation of opioid analgesics in patients who are physically dependent on opioids has resulted in serious withdrawal symptoms, uncontrolled pain, and suicide. Rapid discontinuation has also been associated with attempts to find other sources of opioid analgesics, which may be confused with drug-seeking for abuse. Patients may also attempt to treat their pain or withdrawal symptoms with illicit opioids, such as heroin, and other substances.

When a decision has been made to decrease the dose or discontinue therapy in an opioid-dependent patient taking tramadol hydrochloride extended-release tablets, there are a variety of factors that should be considered, including the dose of tramadol hydrochloride extended-release tablets the patient has

been taking, the duration of treatment, the type of pain being treated, and the physical and psychological attributes of the patient. It is important to ensure ongoing care of the patient and to agree on an appropriate tapering schedule and follow-up plan so that patient and provider goals and expectations are clear and realistic. When opioid analgesics are being discontinued due to a suspected substance use disorder, evaluate and treat the patient, or refer for evaluation and treatment of the substance use disorder. Treatment should include evidence-based approaches, such as medication assisted treatment of opioid use disorder. Complex patients with co-morbid pain and substance use disorders may benefit from referral to a specialist.

There are no standard opioid tapering schedules that are suitable for all patients. Good clinical practice dictates a patient-specific plan to taper the dose of the opioid gradually. For patients on tramadol hydrochloride extended-release tablets who are physically opioid-dependent, initiate the taper by a small enough increment (e.g., no greater than 10% to 25% of the total daily dose) to avoid withdrawal symptoms, and proceed with dose-lowering at an interval of every 2 to 4 weeks. Patients who have been taking opioids for briefer periods of time may tolerate a more rapid taper.

It may be necessary to provide the patient with lower dosage strengths to accomplish a successful taper. Reassess the patient frequently to manage pain and withdrawal symptoms, should they emerge. Common withdrawal symptoms include restlessness, lacrimation, rhinorrhea, yawning, perspiration, chills, myalgia, and mydriasis. Other signs and symptoms also may develop, including irritability, anxiety, backache, joint pain, weakness, abdominal cramps, insomnia, nausea, anorexia, vomiting, diarrhea, or increased blood pressure, respiratory rate, or heart rate. If withdrawal symptoms arise, it may be necessary to pause the taper for a period of time or raise the dose of the opioid analgesic to the previous dose, and then proceed with a slower taper. In addition, monitor patients for any changes in mood, emergence of suicidal thoughts, or use of other substances.

When managing patients taking opioid analgesics, particularly those who have been treated for a long duration and/or with high doses for chronic pain, ensure that a multimodal approach to pain management, including mental health support (if needed), is in place prior to initiating an opioid analgesic taper. A multimodal approach to pain management may optimize the treatment of chronic pain, as well as assist with the successful tapering of the opioid analgesic [see Warnings and Precautions (5.17), Drug Abuse and Dependence (9.3)].

Indications and Usage Section

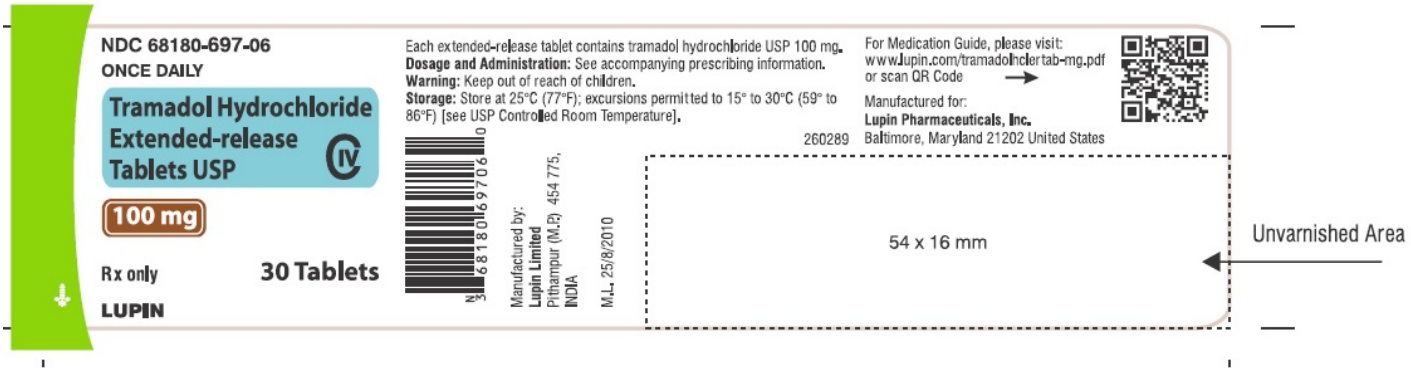
1 INDICATIONS AND USAGE

Tramadol hydrochloride extended-release tablets are indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

Limitations of Use

Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations [see Warnings and Precautions (5.1)] , reserve tramadol hydrochloride extended-release tablets for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
Tramadol hydrochloride extended-release tablets are not indicated as an as-needed (prn) analgesic.

Principal Display Panel



ULTRAM

tramadol hcl 100mg tablet, extended release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:80425-0108(NDC:68180-697)
Route of Administration	ORAL	**DEA Schedule**	CIV

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TRAMADOL HYDROCHLORIDE (UNII: 9N7R477WCK) (TRAMADOL - UNII:39J1LGJ30J)	TRAMADOL HYDROCHLORIDE	100 mg

Product Characteristics			
Color	white	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	L010
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:80425-0108-2	60 in 1 BOTTLE; Type 0: Not a Combination Product	08/19/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA200503	08/19/2014	

Labeler - Advanced Rx Pharmacy of Tennessee, LLC (117023142)

Establishment

Name	Address	ID/FEI	Business Operations
Advanced Rx Pharmacy of Tennessee, LLC		117023142	repack(80425-0108)