ULTRAM- tramadol hcl 50mg tablet
Advanced Rx Pharmacy of Tennessee, LLC

Tramadol HCl 50mg tablet #60

Medication Guide Section

MEDICATION GUIDE

Tramadol Hydrochloride Tablets, USP

(TRAM a dol hye" droe cklo' ride"), 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 much tramadol hydrochloride tablets (overdose). When you first start taking tramadol hydrochloride 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.
- 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 it. Selling or giving away tramadol hydrochloride tablets are against the law.
- Store tramadol hydrochloride 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 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:

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

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.
- Dispose of expired, unwanted, or unused tramadol hydrochloride 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 tablet 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 tablets DO NOT:

- Drive or operate heavy machinery, until you know how tramadol hydrochloride tablets affects 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.

www.sunpharma.com or call 1-800-818-4555

Distributed By:

Sun Pharmaceutical Industries, Inc.

Cranbury, NJ 08512

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

Rev. 10/2019

Adverse Reactions Section

6 ADVERSE REACTIONS

The following serious adverse reactions are described, or described in greater detail, in other sections:

•
Addiction, Abuse, and Misuse [SEE WARNINGS AND PRECAUTIONS (5.1)]
•
Life-Threatening Respiratory Depression [SEE WARNINGS AND PRECAUTIONS (5.3)]
•
Ultra-Rapid Metabolism of Tramadol and Other Risk Factors for Life-threatening
•
Respiratory Depression in CHILDREN [SEE WARNINGS AND PRECAUTIONS (5.4)]
•
Neonatal Opioid Withdrawal Syndrome [SEE WARNINGS AND PRECAUTIONS (5.5)]
•
Interactions with Benzodiazepines or Other CNS Depressants [SEE WARNINGS AND PRECAUTIONS (5.7)]
•
Serotonin Syndrome [SEE WARNINGS AND PRECAUTIONS (5.8)]
•
Seizures [SEE WARNINGS AND PRECAUTIONS (5.9)]
•

Suicide [SEE WARNINGS AND PRECAUTIONS (5.10)]
•
Adrenal Insufficiency [SEE WARNINGS AND PRECAUTIONS (5.11)]
•
Severe Hypotension [SEE WARNINGS AND PRECAUTIONS (5.13)]
•
Gastrointestinal Adverse Reactions [SEE WARNINGS AND PRECAUTIONS (5.15)]
•
Hypersensitivity Reactions [SEE WARNINGS AND PRECAUTIONS (5.16)]
•
Withdrawal [SEE WARNINGS AND PRECAUTIONS (5.17)]

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Tramadol hydrochloride tablets were administered to 550 patients during the double-blind or open-label extension periods in U.S. studies of chronic nonmalignant pain. Of these patients, 375 were 65 years old or older. Table 1 reports the cumulative incidence rate of adverse reactions by 7, 30 and 90 days for the most frequent reactions (5% or more by 7 days). The most frequently reported events were in the central nervous system and gastrointestinal system. Although the reactions listed in the table are felt to be probably related to tramadol hydrochloride tablets administration, the reported rates also include some events that may have been due to underlying disease or concomitant medication. The overall incidence rates of adverse experiences in these trials were similar for tramadol hydrochloride tablets and the active control groups, TYLENOL with Codeine #3 (acetaminophen 300 mg with codeine phosphate 30 mg), and aspirin 325 mg with codeine phosphate 30 mg, however, the rates of withdrawals due to adverse events appeared to be higher in the tramadol hydrochloride tablets groups.

Table 1: Cumulative Incidence of Adverse Reactions for Tramadol Hydrochloride Tablets in Chronic Trials of Nonmalignant Pain (N=427)

	Up to 7 Days	Up to 30 Days	Up to 90 Days
Dizziness/Vertigo	26%	31%	33%
Nausea	24%	34%	40%
Constipation	24%	38%	

46%
Headache
18%
26%
32%
Somnolence
16%
23%
25%
Vomiting
9%
13%
17%
Pruritus
8%
10%
11%
“CNS Stimulation” 1
7%
11%
14%
Asthenia
6%
11%
12%
Sweating
6%
7%
9%
Dyspepsia
5%
9%
13%
Dry Mouth
5%
9%
10%

Diarrhea

5%

6%

10%

1 “CNS Stimulation” is a composite of nervousness, anxiety, agitation, tremor, spasticity, euphoria, emotional
lability and hallucinations

Incidence 1% to Less than 5% Possibly Causally Related

The following lists adverse reactions that occurred with an incidence of 1% to less than 5% in clinical trials, and for which the possibility of a causal relationship with tramadol hydrochloride tablets exist.

Body as a Whole: Malaise.

Cardiovascular: Vasodilation.

Central Nervous System: Anxiety, Confusion, Coordination disturbance, Euphoria, Miosis, Nervousness, Sleep disorder.

Gastrointestinal: Abdominal pain, Anorexia, Flatulence.

Musculoskeletal: Hypertonia.

Skin: Rash.

Special Senses: Visual disturbance.

Urogenital: Menopausal symptoms, Urinary frequency, Urinary retention.

Incidence Less than 1%, Possibly Causally Related

The following lists adverse reactions that occurred with an incidence of less than 1% in clinical trials of tramadol and/or reported in post-marketing experience with tramadol-containing products.

Body as a Whole: Accidental injury, Allergic reaction, Anaphylaxis, Death, Suicidal tendency, Weight loss, Serotonin syndrome (mental status change, hyperreflexia, fever, shivering, tremor, agitation, diaphoresis, seizures and coma).

Cardiovascular: Orthostatic hypotension, Syncope, Tachycardia.

Central Nervous System: Abnormal gait, Amnesia, Cognitive dysfunction, Depression, Difficulty in concentration, Hallucinations, Paresthesia, Seizure, Tremor.

Respiratory: Dyspnea.

Skin: Stevens-Johnson syndrome/Toxic epidermal necrolysis, Urticaria, Vesicles.

Special Senses: Dysgeusia.

Urogenital: Dysuria, Menstrual disorder.

Other Adverse Experiences, Causal Relationship Unknown

A variety of other adverse events were reported infrequently in patients taking tramadol hydrochloride tablets during clinical trials and/or reported in post-marketing experience. A causal relationship between tramadol hydrochloride tablets and these events has not been determined. However, the most significant events are listed below as alerting information to the physician.

Cardiovascular: Abnormal ECG, Hypertension, Hypotension, Myocardial ischemia, Palpitations, Pulmonary edema, Pulmonary embolism.

Central Nervous System: Migraine.

Gastrointestinal: Gastrointestinal bleeding, Hepatitis, Stomatitis, Liver failure.

Laboratory Abnormalities: Creatinine increase, Elevated liver enzymes, Hemoglobin decrease, Proteinuria.

Sensory: Cataracts, Deafness, Tinnitus.

6.2 Postmarketing Experience

The following adverse reactions have been identified during post-approval use of tramadol hydrochloride tablets. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Serotonin syndrome: Cases of serotonin syndrome, a potentially life-threatening condition, have been reported during concomitant use of opioids with serotonergic drugs.

Adrenal insufficiency: Cases of adrenal insufficiency have been reported with opioid use, more often following greater than one month of use.

Androgen deficiency: Cases of androgen deficiency have occurred with chronic use of opioids [SEE CLINICAL PHARMACOLOGY (12.2)].

QT prolongation/torsade de pointes: Cases of QT prolongation and/or torsade de pointes have been reported with tramadol use. Many of these cases were reported in patients taking another drug labeled for QT prolongation, in patients with a risk factor for QT prolongation (e.g., hypokalemia), or in the overdose setting.

Eye disorders – mydriasis

Metabolism and nutrition disorders – Cases of hypoglycemia have been reported very rarely in patients taking tramadol. Most reports were in patients with predisposing risk factors, including diabetes or renal insufficiency, or in elderly patients.

Nervous system disorders – movement disorder, speech disorder

Psychiatric disorders – delirium

Indications and Usage

1 INDICATIONS AND USAGE

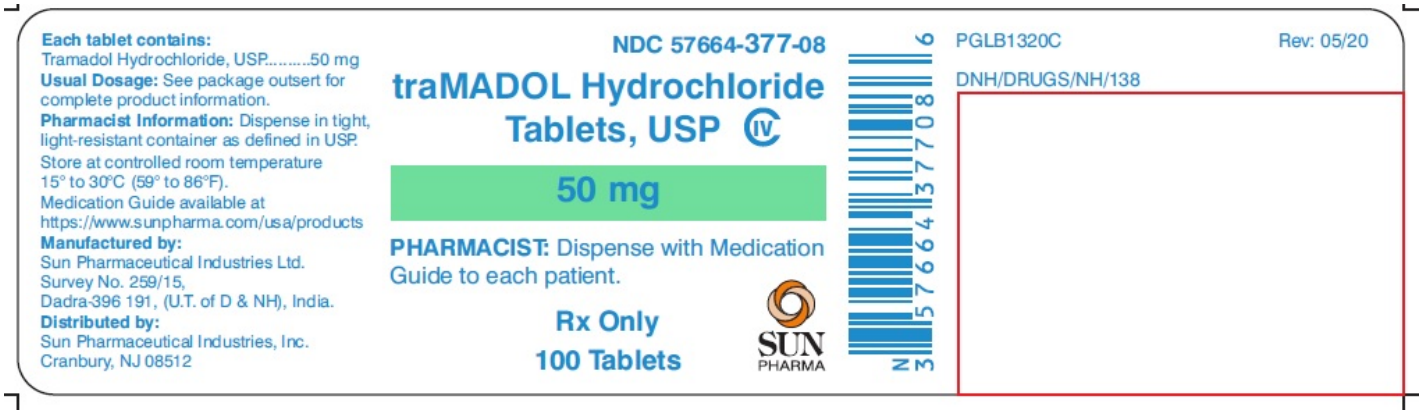
Tramadol hydrochloride tablets are indicated in adults for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Limitations of Use

Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses [see WARNINGS AND PRECAUTIONS (5.1)], reserve tramadol hydrochloride tablets for use in patients for whom alternative treatment options [e.g., non-opioid analgesics]:

- Have not been tolerated or are not expected to be tolerated.
- Have not provided adequate analgesia or are not expected to provide adequate analgesia.

Principal Display Panel



ULTRAM

tramadol hcl 50mg tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:80425-0058(NDC:57664-377)
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	50 mg

Product Characteristics			
Color	white	**Score**	no score
Shape	CAPSULE	**Size**	13mm
Flavor		**Imprint Code**	377
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:80425-0058-2	60 in 1 BOTTLE; Type 0: Not a Combination Product	06/22/2002	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075964	06/22/2002	

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

Establishment

Name	Address	ID/FEI	Business Operations
Advanced Rx Pharmacy of Tennessee, LLC		117023142	repack(80425-0058)