ADVAGEN

25mg IS THE RECOMMENDED STARTED DOSE FOR TRAMADOL

TRAMADOL HYDROCHLORIDE TABLETS, USP 25 mg

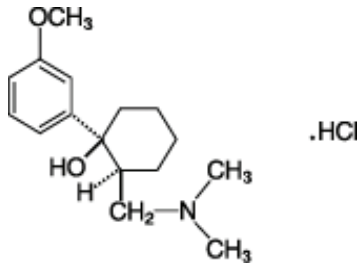
sales@advagenpharma.com
www.advagenpharma.com

Tramadol Hydrochloride Tablets, USP 25 mg

Advagen Pharma Ltd.

DESCRIPTION

Tramadol Hydrochloride Tablets, USP for oral use, are an opioid agonist. The chemical name for tramadol hydrochloride is (±)cis-2-[(dimethylamino) methyl]-1-(3-methoxyphenyl) cyclohexanol hydrochloride. The structural formula is:



The molecular weight of tramadol hydrochloride is 299.8. Tramadol hydrochloride is a white crystalline powder. It is readily soluble in water and ethanol and has a pKa of 9.41. Then-octanol/water log partition coefficient (logP) is 1.35 at pH 7. Tramadol Hydrochloride Tablets, USP 25 mg, 50 mg and 100 mg contain 25 mg, 50 mg and 100 mg of tramadol hydrochloride respectively and are white in color. Inactive ingredients in the tablet are hypromellose, lactose anhydrous, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, pregelatinized starch, sodium starch glycolate and titanium dioxide.

INDICATIONS AND USAGE

Tramadol hydrochloride is an opioid agonist 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 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.

DOSAGE FORMS AND STRENGTHS

Tablets: 25 mg, 50 mg and 100 mg

DOSAGE AND ADMINISTRATION

Use the lowest effective dosage for the shortest duration consistent with individual patient treatment goals

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

Monitor patients closely for respiratory depression, especially within the first 24-72 hours of initiating therapy and following dosage increases with tramadol hydrochloride tablets and adjust the dosage accordingly

OVERDOSAGE

Clinical Presentation

Acute overdosage with tramadol hydrochloride tablets can be manifested by respiratory depression,somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, constricted pupils, and, in some cases, pulmonary edema, bradycardia, QT prolongation, hypotension, partial or complete airway obstruction, atypical snoring, seizures, and death. Marked mydriasis rather than miosis may be seen with hypoxia in overdose situations.

Deaths due to overdose have been reported with abuse and misuse of tramadol Review of case reports has indicated that the risk of fatal overdose is further increased when tramadol is abused concurrently with alcohol or other CNS depressants, including other opioids.

HOW SUPPLIED/STORAGE AND HANDLING

Tramadol Hydrochloride Tablets, USP 25 mg are white to off white round shaped film coated tablet debossed with "A7" on one side and "/\" on other side.

Bottles of 30 tablets.....NDC 72888-162-30
Bottles of 100 tablets..... NDC 72888-162-01
Bottles of 500 tablets..... NDC 72888-162-05
Bottles of 1,000 tablets..... NDC 72888-162-00

Store tramadol hydrochloride tablets securely and dispose of properly

Medication Guide

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 or call 911 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. Talk to your healthcare provider about naloxone, a medicine for the emergency treatment of an opioid overdose.

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 is 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, opioid overdose, 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 lifethreatening 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 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 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 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 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 tablets. Call your doctor for medical advice about side effects. You may report side effects to Advagen Pharma Ltd, at 866-488-0312 or FDA at 1-800-FDA-1088.

For more information go to dailymed.nlm.nih.gov.

Manufactured by:
Rubicon Research Private Limited,
Ambernath, Dist: Thane, 421506
India

Distributed by:
Advagen Pharma Ltd
666 Plainsboro Road
Plainsboro Suite 605,
Plainsboro, NJ, 08536, USA
Revision: 12/2023

NDC	Description	Strength	Package Size - Bottles
NDC 72888-162-30	Tramadol Hydrochloride Tablets	25 mg	30ct
NDC 72888-162-01			100ct
NDC 72888-162-05			500ct
NDC 72888-162-00			1,000ct

Medication Guide available at
www.advagenpharma.com/medguide/Tramadol HydrochlorideTablets