EMERGENCY OVERVIEW

Each Tramadol Hydrochloride Tablet USP intended for oral administration contains Tramadol Hydrochloride and excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

Section 1. Identification

Identification of the product

Product name: Tramadol Hydrochloride Tablets USP

Formula: C16H25NNO2

Chemical Name: (±) cis-2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol hydrochloride

Manufacturer / supplier identification

Company: Cadila Healthcare Ltd. Ahmedabad, India


Contact for information: Tel.: +91 79 6868100 Fax: +91 79 3750319

Emergency Telephone No. Tel.: +91 79 6868100

Recommended use / Therapeutic Category Opioid Analgesic

Restriction on Use / Contraindications Tramadol hydrochloride tablets should not be administered to patients who have previously demonstrated hypersensitivity to tramadol, any other component of this product or opioids. Tramadol hydrochloride tablets are contraindicated in any situation where opioids are contraindicated, including
Section 2. Hazard(s) Information

Dose and Administration  
**Adults (17 years of age and over)**
For patients with moderate to moderately severe chronic pain not requiring rapid onset of analgesic effect, the tolerability of tramadol hydrochloride tablets can be improved by initiating therapy with a titration regimen: The total daily dose may be increased by 50 mg as tolerated every 3 days to reach 200 mg/day (50 mg q.i.d.). After titration, tramadol hydrochloride tablets 50 to 100 mg can be administered as needed for pain relief every 4 to 6 hours **not to exceed 400 mg/day**.

Adverse Effects  
**Body as a whole:** Malaise

**Cardiovascular System:** Vasodialation

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

**Gastrointestinal:** Abdominal pain, Anorexia, Flatulence

**Musculoskeletal:** Hypertonia.

**Skin:** Rash.

**Special Senses:** Visual disturbance.

**Urogenital:** Menopausal symptoms, Urinary frequency, Urinary retention.

Over Dose Effects  
Acute overdosage with tramadol can be manifested by respiratory depression, somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, constricted pupils, seizures, bradycardia, hypotension, cardiac arrest and death. 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.

Contraindications  
Tramadol hydrochloride tablets should not be administered to patients who have previously demonstrated hypersensitivity to tramadol, any other
component of this product or opioids. Tramadol hydrochloride tablets are contraindicated in any situation where opioids are contraindicated, including acute intoxication with any of the following: alcohol, hypnotics, narcotics, centrally acting analgesics, opioids or psychotropic drugs. Tramadol hydrochloride tablets may worsen central nervous system and respiratory depression in these patients.

**Medical Condition**

**Seizure Risk**
Seizures have been reported in patients receiving tramadol hydrochloride within the recommended dosage range. Spontaneous post-marketing reports indicate that seizure risk is increased with doses of tramadol hydrochloride above the recommended range. Concomitant use of tramadol hydrochloride increases the seizure risk in patients taking:

- Selective serotonin reuptake inhibitors (SSRI antidepressants or anorectics),
- Tricyclic antidepressants (TCAs), and other tricyclic compounds (e.g., cyclobenzaprine, promethazine, etc.), or
- Other opioids.

Administration of tramadol hydrochloride may enhance the seizure risk in patients taking:
- MAO inhibitors and Serotonin Reuptake Inhibitors,
- Neuroleptics, or
- Other drugs that reduce the seizure threshold.

Risk of convulsions may also increase in patients with epilepsy, those with a history of seizures, or in patients with a recognized risk for seizure (such as head trauma, metabolic disorders, alcohol and drug withdrawal, CNS infections). In tramadol hydrochloride overdose, naloxone administration may increase the risk of seizure.

**Suicide Risk**

- Do not prescribe tramadol hydrochloride tablets for patients who are suicidal or addiction-prone.
- Prescribe tramadol hydrochloride tablets with caution for patients who are taking tranquilizers or antidepressant drug and patients who use alcohol in excess and who suffer from emotional disturbance or depression.

**Pregnancy Comments**
Tramadol hydrochloride is not recommended for obstetrical preoperative medication or for post-delivery analgesia in nursing mothers because its safety in infants and newborns has not been studied. Following a single IV 100 mg dose of tramadol, the cumulative excretion in breast milk within 16 hours postdose was 100 mcg of tramadol (0.1% of the maternal dose) and 27 mcg of M1.
Strength: 50mg. Pack Size: Bottles of 100/500/1000 Tablets Blisters of 100 Tablets

Pregnancy Category C

Section 3. Composition / information on ingredient

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<th>Component</th>
<th>Exposure Limit</th>
<th>CAS No.</th>
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<tbody>
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<td>Inactive Ingredients:</td>
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</table>

Section 4. First - aid measures

General
Remove from exposure. Remove contaminated Clothing. Person developing serious hypersensitivity reaction must receive medical attention.

Overdose Treatment
In the treatment of tramadol overdosage, primary attention should be given to the reestablishment of a patent airway and institution of assisted or controlled ventilation. Supportive measures (including oxygen and vasopressors) should be employed in the management of circulatory shock and pulmonary edema accompanying overdose as indicated. Cardiac arrest or arrhythmias may require cardiac massage or defibrillation.

Section 5. Fire - fighting measures

Flash point Not Found
Upper Flammable Limit: Not Found
Auto-Ignition Temperature: Not Found
Lower Flammable Limit: Not Found
Extinguishing Media Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.
Fire and Explosion Hazard This material is assumed to be combustible. As with all dry powders it is advisable to ground...
Fire Fighting Procedure

As with all fires, evacuate personnel to a safe area. Fire fighter should use self-contained breathing equipment and protective clothing.

Section 6. Accidental Release Measures

Spill Response

Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.

Section 7. Handling and Storage

Storage

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Dispense in a tight container.

Incompatibilities:

No data available.

Section 8. Exposure controls / personal protection

Respiratory Protection

Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to generate, use of suitable dust mask would be appropriate.

Skin Protection

Skin protection is not normally necessary, however it is good practice to avoid contact with chemical to use suitable gloves when handling.

Eye protection

Eye protection is not normally necessary. If concerned wear protective goggles or glasses. Wash hands prior to touching eye and in particular handling contact lenses.

Protective Clothing

Protective clothing is not normally necessary, however it is good practice to use apron.

Engineering Control

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

mechanical equipment in contact with the dry material to dissipate the potential build-up of static electricity.
Section 9. Physical and chemical properties

**Appearance**
Tramadol Hydrochloride Tablets, USP 50 mg are white to off-white, round, film-coated tablets debossed with ‘319’ on one side and plain on the other side.

**Solubility in water**
No Data Available

**Boiling point**
No Data Available

**Evaporation rate**
No Data Available

**Reactivity in water**
No Data Available

**% Volatile by volume**
No Data Available

**Odour**
Odourless

**Melting Point**
No Data Available

**Vapour density**
No Data Available

**Evaporation rate**
No Data Available

**Specific gravity**
No Data Available

**Vapour pressure**
No Data Available

**Other information**
Tramadol hydrochloride, USP is a white, bitter, crystalline and odorless powder. It is readily soluble in water and ethanol and has a pKₐ of 9.41. The n-octanol/water log partition coefficient (logP) is 1.35 at pH 7. The molecular weight of tramadol hydrochloride is 299.84.

Section 10. Stability and Reactivity

**Condition to avoid**
Avoid exposure to extreme heat, light and moisture.

**Stable**
Stable under normal ambient and anticipated storage and handling conditions.

**Decomposition Products**
No Data Available

**Hazardous Reaction**
No data available.

**Incompatibilities:**
No Data available.

Section 11. Toxicological information

**General**
Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this species formulation.

**Target organ**
Eye contact, Skin contact and inhalation is not great risk as this product is Tablets.

**Other**
No data available

Section 12. Ecological information

Do not allow product to enter drinking water supplies, waste water or soil.
Safety Data Sheet
TRAMADOL HYDROCHLORIDE TABLETS USP

Strength: 50mg. Pack Size: Bottles of 100/500/1000 Tablets
Blisters of 100 Tablets
Revision No.: 02

Section 13. Disposal Consideration
Dispose the waste in accordance with all applicable Federal, State and local laws.

Section 14. Transport Information
The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG).

Section 15. Regulatory Information
Generic Medicine. Approved by USFDA & the ANDA Number is 090-404

Section 16. Other information
None

Date of issue: 28/05/2015 Supersedes edition of: 01

The information contained herein is based on the state of our knowledge. It characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.