

## Safety Data Sheet

### TRAZODONE HYDROCHLORIDE TABLETS

Strength: 50 mg, 100 mg, 150 mg , 300 mg and 150 mg

Pack Size: 30's, 90's 100's, 500's and 1000's Tablets per bottle and Carton of 100 Tablets  
(10 x 10 unit Dose)

Revision No.: 00

#### EMERGENCY OVERVIEW

Each Trazodone Hydrochloride Tablets intended for oral administration contains Trazodone 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

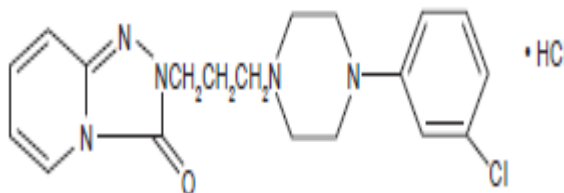
**Product Name:**

2-[3-[4-(3-chlorophenyl)-1-piperazinyl]propyl]-1,2,4-triazolo[4,3-a]pyridin-3(2H)-one hydrochloride.

**Formula:**

C<sub>19</sub>H<sub>22</sub>ClN<sub>5</sub>O•HCl

**Chemical Name:**



##### Manufacturer / supplier identification

**Company:**

**Cadila Healthcare Ltd., Matoda, India**

**Address:**

Cadila Healthcare Limited, Plot No- 1A/1 & 2, Pharmez Special Economic Zone, Sarkhej- Bavla N.H. No. 8A, Near Village Matoda, Tal. Sanand, Dist. Ahmedabad-382 213, India

**Contact for information:**

Tel: +91-79-26868100 Fax: +91-79-26868533

**Emergency Telephone No.**

Tel: +91-79-26868101

**Recommended use /  
Therapeutic Category  
Restriction on Use /  
Contraindications:**

Trazodone hydrochloride tablets are indicated for the treatment of major depressive disorder (MDD) in adults.

Trazodone hydrochloride tablets are contraindicated in:

- Patients taking, or within 14 days of stopping, monoamine oxidase inhibitors (MAOIs), including MAOIs such as linezolid or intravenous methylene blue, because of an increased risk of serotonin syndrome

## Safety Data Sheet

### TRAZODONE HYDROCHLORIDE TABLETS

Strength: 50 mg, 100 mg, 150 mg , 300 mg and 150 mg

Pack Size: 30's, 90's 100's, 500's and 1000's Tablets per bottle and Carton of 100 Tablets

(10 x 10 unit Dose)

Revision No.: 00

#### Section 2. Hazard(s) Identification

##### Dose and Administration

##### Dose Selection

An initial dose of 150 mg/day in divided doses is suggested. The dosage should be initiated at a low-dose and increased gradually, noting the clinical response and any evidence of intolerance. Occurrence of drowsiness may require the administration of a major portion of the daily dose at bedtime or a reduction of dosage.

The dose may be increased by 50 mg/day every 3 to 4 days. The maximum dose for outpatients usually should not exceed 400 mg/day in divided doses. Inpatients (i.e., more severely depressed patients) may be given up to but not in excess of 600 mg/day in divided doses.

Once an adequate response has been achieved, dosage may be gradually reduced, with subsequent adjustment depending on therapeutic response.

##### Important Administration Instructions

Trazodone hydrochloride tablets can be swallowed whole or administered as a half tablet by breaking the tablet along the score line.

Trazodone hydrochloride tablets should be taken shortly after a meal or light snack.

##### Adverse Effects

The following serious adverse reactions are described elsewhere in the labelling:

Suicidal Thoughts and Behaviour in Children, Adolescents and Young Adults

- Serotonin Syndrome
- Cardiac Arrhythmias
- Orthostatic Hypotension and Syncope
- Increased Risk of Bleeding
- Priapism
- Activation of Mania or Hypomania
- Discontinuation Syndrome
- Potential for Cognitive and Motor Impairment
- Angle-Closure Glaucoma
- Hyponatremia

## Safety Data Sheet

### TRAZODONE HYDROCHLORIDE TABLETS

Strength: 50 mg, 100 mg, 150 mg , 300 mg and 150 mg

Pack Size: 30's, 90's 100's, 500's and 1000's Tablets per bottle and Carton of 100 Tablets  
(10 x 10 unit Dose)

Revision No.: 00

<b>Over Dose Effect</b>	<p>Death from overdose has occurred in patients ingesting trazodone and other CNS depressant drugs concurrently (alcohol; alcohol and chloral hydrate and diazepam; amobarbital; chlordiazepoxide; or meprobamate).</p> <p>The most severe reactions reported to have occurred with overdose of trazodone alone have been priapism, respiratory arrest, seizures, and ECG changes, including QT prolongation. The reactions reported most frequently have been drowsiness and vomiting. Overdosage may cause an increase in incidence or severity of any of the reported adverse reactions.</p> <p>There is no specific antidote for trazodone hydrochloride overdose.</p>
<b>Contraindications</b>	<p>Trazodone hydrochloride tablets are contraindicated in:</p> <ul style="list-style-type: none"><li>• Patients taking, or within 14 days of stopping, monoamine oxidase inhibitors</li></ul>
<b>Pregnancy Comments</b>	<p><b>Teratogenic Effects</b></p> <p>Trazadone hydrochloride has been shown to cause increased fetal resorption and other adverse effects on the fetus in the rat when given at dose levels approximately 6 to 9 times the maximum recommended human dose (MRHD) of 400 mg/day on mg/m<sup>2</sup> in adolescents. There was also an increase in congenital anomalies in the rabbit at approximately 6 to 17 times the MRHD on mg/m<sup>2</sup> basis in adolescents. There are no adequate and well-controlled studies in pregnant women. Trazodone hydrochloride should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.</p> <p><b>Animal Data</b></p> <p>No teratogenic effects were observed when trazodone was given to pregnant rats and rabbits during the period of organogenesis at oral doses up to 450 mg/kg/day. This dose is 9 and 17 times, in rats and rabbits, respectively, the maximum recommended human dose (MRHD) of 400 mg/day on mg/m<sup>2</sup> basis in adolescents. Increased fetal resorption and other adverse effects on the fetus in rats at 6 to 9 times the MRHD and increase in congenital anomalies in rabbits at 6 to 17 times the MRHD on mg/m<sup>2</sup> basis in adolescents were observed.</p>
<b>Pregnancy Category</b>	C

## Safety Data Sheet

### TRAZODONE HYDROCHLORIDE TABLETS

Strength: 50 mg, 100 mg, 150 mg , 300 mg and 150 mg

Pack Size: 30's, 90's 100's, 500's and 1000's Tablets per bottle and Carton of 100 Tablets

(10 x 10 unit Dose)

Revision No.: 00

Section 3. Composition / information on ingredients		
Component	Exposure Limit	CAS No.
<b>Principle Component:</b>		
Trazadone HCL	Not Found	25332-39-2
<b>Inactive Ingredients:</b>		
Microcrystalline Cellulose	Not Found	9004-34-6
Pregelatinized Starch 1500	Not Found	Not Available
Sodium Lauryl Sulphate	Not Found	151-21-3
Sodium Starch Glycolate	Not Found	9063-38-1
Colloidal Silicon Dioxide	Not Found	7631-86-9
Magnesium stearate	Not Found	557-04-0
<b>Section 4. First -aid measures</b>		
<b>General</b>	<ul style="list-style-type: none"><li>• <b>After inhalation:</b> Move to fresh air in case of accidental inhalation. assure fresh air breathing.</li><li>• <b>After skin contact:</b> Rinse skin with water/shower</li><li>• <b>After eye contact:</b> Rinse with water while holding the eyes wide open. Contact lenses should be removed.</li><li>• <b>After swallowing:</b> Rinse mouth out with water</li><li>• <b>Information for doctor:</b></li><li>• <b>Most important symptoms and effects, acute and delayed-</b> No further relevant information available.</li><li>• <b>Indication of any immediate medical attention and special treatment needed-</b> No further relevant information available.</li></ul>	

## Safety Data Sheet

### TRAZODONE HYDROCHLORIDE TABLETS

Strength: 50 mg, 100 mg, 150 mg , 300 mg and 150 mg

Pack Size: 30's, 90's 100's, 500's and 1000's Tablets per bottle and Carton of 100 Tablets  
(10 x 10 unit Dose)

Revision No.: 00

Overdose Treatment	<p>Death from overdose has occurred in patients ingesting trazodone and other CNS depressant drugs concurrently (alcohol; alcohol and chloral hydrate and diazepam; amobarbital; chlordiazepoxide; or meprobamate).</p> <p>The most severe reactions reported to have occurred with overdose of trazodone alone have been priapism, respiratory arrest, seizures, and ECG changes, including QT prolongation. The reactions reported most frequently have been drowsiness and vomiting. Overdosage may cause an increase in incidence or severity of any of the reported adverse reactions.</p> <p>There is no specific antidote for trazodone hydrochloride overdose.</p> <p>In managing overdosage, consider the possibility of multiple drug involvement. For current information on the management of poisoning or overdose, contact a poison control centre</p>
<b>Section 5. Fire -fighting measures</b>	
	<p><b>Extinguishing media</b></p> <p>· <b>Suitable extinguishing agents:</b> Use extinguishing media appropriate for surrounding fire. Extinguishing blanket. Carbon dioxide. Dry powder</p> <p><b>Special hazards arising from the substance or mixture</b></p> <p>Stable under normal conditions.</p> <p>· <b>Advice for firefighters</b></p> <p>Small amounts: Use normal individual fire protective equipment. Large amounts: Not</p> <p>· <b>Protective equipment:</b></p> <p>Hand protection : Gloves Skin and body protection : Lab coat Respiratory protection : Quarter mask (DIN EN 140)</p> <p>No additional information available</p>
<b>Specific hazards arising from the chemical</b>	
<b>Special protective equipment and precautions for firefighters</b>	Use normal individual fire protective equipment
<b>General fire hazards</b>	No unusual fire or explosion hazards noted

## Safety Data Sheet

### TRAZODONE HYDROCHLORIDE TABLETS

Strength: 50 mg, 100 mg, 150 mg , 300 mg and 150 mg

Pack Size: 30's, 90's 100's, 500's and 1000's Tablets per bottle and Carton of 100 Tablets

(10 x 10 unit Dose)

Revision No.: 00

#### Section 6. Accidental Release Measures

**Personal precautions, protective equipment and emergency procedures** Avoid raising dust. Wear suitable protective clothing, gloves and eye or face protection.

**Environmental precautions:** No additional information available

**Methods and material for containment and cleaning up:** Sweep spilled substance into containers; if appropriate, moisten first to prevent dusting. Ensure waste is collected and contained. Clean thoroughly. Poorly soluble in water. Clean with the help of detergents.

#### Section 7. Handling and Storage

**Storage:** Store at 20 to 25°C (68 to 77°F)  
Dispense in a tightly closed container with a child-resistant closure (as required).  
Keep out of the reach of children.

**Precautions for safe handling:** Keep it dry & in a cool, well ventilated place away from heat. Store in original container

**Information about fire - and explosion protection:** No special measures required.

#### Section 8. Exposure controls / personal protection

**Respiratory Protection** Quarter mask (DIN EN 140)

**Skin protection** For prolonged or repeated skin contact use suitable protective gloves.

**Eye/face protection** If contact is likely, safety glasses with side shields are recommended.

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

**Biological limit values** No biological exposure limits noted for the ingredient(s).

**Exposure guidelines** General ventilation normally adequate.

**Thermal hazards** Wear appropriate thermal protective clothing, when necessary.

## Safety Data Sheet

### TRAZODONE HYDROCHLORIDE TABLETS

Strength: 50 mg, 100 mg, 150 mg , 300 mg and 150 mg

Pack Size: 30's, 90's 100's, 500's and 1000's Tablets per bottle and Carton of 100 Tablets  
(10 x 10 unit Dose)

Revision No.: 00

**General hygiene considerations** Keep away from foodstuffs, beverages and feed.  
Wash hands before breaks and at the end of work.  
Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

**Engineering controls** 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.

#### Section 9. Physical and chemical properties

##### Appearance

Description of **Trazodone Hydrochloride Tablets USP 50 mg**: Whit to Off-white, round shape, biconvex bevelled tablets, bisect on one side and plain on other side. The bisected side of tablet is debossed with "8" on upper side of bisect and "05" on lower side of bisect

Description of **Trazodone Hydrochloride Tablets USP 100 mg**: Whit to Off-white, round shape, biconvex bevelled tablets, bisect on one side and plain on other side. The bisected side of tablet is debossed with "8" on upper side of bisect and "06" on lower side of bisect

Description of **Trazodone Hydrochloride Tablets USP 150 mg**: Whit to Off-white, oval shape, flat faced bevelled tablets, having one full bisect and two trisect notches on one side and two trisect on other side. The full bisected side of tablet is debossed with "8" on one side of bisect and "07" on other bisect segment.

Description of **Trazodone Hydrochloride Tablets USP 300 mg**: Whit to Off-white, oval shape, flat faced bevelled tablets, having one full bisect and two trisect notches on one side and two trisect on other side. The full bisected side of tablet is debossed with "8" on one side of bisect and "08" on other bisect segment.

**Safety Data Sheet****TRAZODONE HYDROCHLORIDE TABLETS****Strength:** 50 mg, 100 mg, 150 mg , 300 mg and 150 mg**Pack Size:** 30's, 90's 100's, 500's and 1000's Tablets per bottle and Carton of 100 Tablets

(10 x 10 unit Dose)

**Revision No.:** 00

<b>Solubility</b>	Not available.	<b>Odour</b>	Not available.
<b>Boiling point</b>	Not available.	<b>Melting Point</b>	Not available.
<b>Evaporation rate</b>	Not available.	<b>Vapour density</b>	Not available.
<b>Reactivity in water</b>	Not available.	<b>Vapour pressure</b>	Not available.
<b>% Volatile by volume</b>	Not available.	<b>Specific gravity</b>	Not available.
<b>Section 10. Stability and Reactivity</b>			
<b>Conditions to avoid</b>	Contact with incompatible materials.		
<b>Stable</b>	<b>Reactivity</b> The product is stable and non-reactive under normal conditions of use, storage and transport.		
<b>Chemical stability</b>	Material is stable under normal conditions.		
<b>Hazardous reactions</b>	No dangerous reaction known under conditions of normal use.		
<b>Decomposition products</b>	When heated to decomposition, emits dangerous fumes.		
<b>Incompatible materials</b>	Strong Oxidizing agent		
<b>Section 11. Toxicological information</b>			
<b>General</b>	Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation.		
<b>Ingestion</b>	Health injuries are not known or expected under normal use. Expected to be a low ingestion hazard. However, ingestion is not likely to be a primary route of occupational exposure.		
<b>Other</b>	Not Available		



**Safety Data Sheet****TRAZODONE HYDROCHLORIDE TABLETS****Strength:** 50 mg, 100 mg, 150 mg , 300 mg and 150 mg**Pack Size:** 30's, 90's 100's, 500's and 1000's Tablets per bottle and Carton of 100 Tablets

(10 x 10 unit Dose)

**Revision No.:** 00

<b>Symptoms related to the physical, chemical and Toxicological characteristics</b>	Not Available
<b>Information on toxicological effects</b>	
<b>Acute toxicity</b>	No drug or dose related occurrence of carcinogenesis was evident in rats receiving oral doses up to 7.3 times the maximum recommended human dose of 400mg/day on mg/m2 basis
<b>Further information</b>	NA
<b>Section 12. Ecological information</b>	
	Poorly soluble in water. No data available on ecotoxicity.
<b>Section 13. Disposal Consideration</b>	
	Dispose the waste in accordance with all applicable Federal, State and local laws.
<b>Section 14. Transport Information</b>	
	The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG). In accordance with ADR / RID / IMDG / IATA / ADN
<b>Section 15. Regulatory Information</b>	
	Generic Medicine. Under Approval by USFDA & the ANDA Number is 205253
<b>Section 16. Other information</b>	
	None

**Date of issue:** 31/08/17**Supersedes edition:** New Edition

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