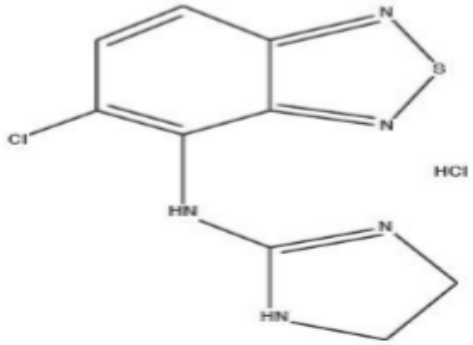
Safety Data Sheet
TIZANIDINE TABLETS USP
Strength: 2 mg, and 4 mg
Pack Size: 30's, 150's, 300's 1000's Tablets per bottle, and Blister Pack of (10 x 10) unit-dose tablets.

Revision No.: 00

EMERGENCY OVERVIEW
Each TIZANIDINE TABLETS intended for oral administration contains TIZANIDINE TABLETS 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:	TIZANIDINE TABLETS USP
Formula:	C9H8ClN5S-HCl
Chemical Name:	5-chloro-4-(2-imidazolin-2-ylamino)-2,1,3benzothiadiazole monohydrochloride
Formula:	

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	The recommended starting dose is 2 mg. Because the effect of tizanidine tablet peaks at approximately 1 to 2 hours post-dose and dissipates between 3 to 6 hours post-dose, treatment can be repeated at 6 to 8 hour intervals, as needed, to a maximum of three doses in 24 hours.
Restriction on Use /	Not available

Contraindications:	
Section 2. Hazard(s) Identification	
Dose and Administration	maximum of 3 doses in 24 hours, Dosage can be increased by 2 mg to 4 mg per dose, with 1 to 4 days between increases; total daily dose should not exceed 36 mg, Tizanidine pharmacokinetics differs between tablets and capsules, and when taken with or without food. These differences could result in a change in tolerability and control of symptoms, to discontinue tizanidine tablets, decrease dose slowly to minimize the risk of withdrawal and rebound hypertension, tachycardia, and hypertonia.
Adverse Effects	The most common adverse reactions (greater than 2% of 264 patients taking tizanidine and greater than in placebo-treated patients in three multiple dose, placebo-controlled studies) were dry mouth, somnolence, asthenia, dizziness, urinary tract infection, constipation, liver function tests abnormal, vomiting, speech disorder, amblyopia, urinary frequency, flu syndrome, SGPT/ALT increased, dyskinesia, nervousness, pharyngitis, and rhinitis
Over Dose Effect	A review of the safety surveillance database revealed cases of intentional and accidental tizanidine overdose. Some of the cases resulted in fatality and many of the intentional overdoses were with multiple drugs including CNS depressants. The clinical manifestations of tizanidine overdose were consistent with its known pharmacology. In the majority of cases a decrease in sensorium was observed including lethargy, somnolence, confusion and coma. Depressed cardiac function is also observed including most often bradycardia and hypotension. Respiratory depression is another common feature of tizanidine overdose. Should overdose occur, basic steps to ensure the adequacy of an airway and the monitoring of cardiovascular and respiratory systems should be undertaken. Tizanidine is a lipid-soluble drug, which is slightly soluble in water and methanol. Therefore, dialysis is not likely to be an efficient method of removing drug from the body. In general, symptoms resolve within one to three days following discontinuation of tizanidine and administration of appropriate therapy. Due to the similar mechanism of action,

	symptoms and management of tizanidine overdose are similar to that following clonidine overdose. For the most recent information concerning the management of overdose, contact a poison control center.
Contraindications	Tizanidine tablets are contraindicated in patientstaking potent inhibitors of CYP1A2, such as fluvoxamine or ciprofloxacin.
Pregnancy Comments	Tizanidine has not been studied in pregnant women. Tizanidine should be given to pregnant women only if the benefit outweighs the risk to the unborn fetus. Reproduction studies performed in rats at a dose of 3 mg/kg, equal to the maximum recommended human dose on a mg/m2 basis, and in rabbits at 30 mg/kg, 16 times the maximum recommended human dose on a mg/m2 basis, did not show evidence of teratogenicity. Tizanidine at doses that are equal to and up to 8 times the maximum recommended human dose on a mg/m2 basis increased gestation duration in rats. Prenatal and postnatal pup loss was increased and developmental retardation occurred. Post-implantation loss was increased in rabbits at doses of 1 mg/kg or greater, equal to or greater than 0.5 times the maximum recommended human dose on a mg/m2 basis.
Pregnancy Category	**C**

Section 3. Composition / information on ingredients

Component	**Exposure Limit**	**CAS No.**
Principle Component:		
TIZANIDINE HYDROCHLORIDE.	Not Found	64461-82-1
Inactive Ingredients:		
ANHYDROUS LACTOSE (SUPERTAB 21AN)	Not Found	63-42-3
MICROCRYSTALLINE CELLULOSE (COMPRECEL M102D+)	Not Found	9004-34-6
CROSCARMELLOSE SODIUM (AC-DI-SOL)	Not Found	74811-65-7

STEARIC ACID (STELLIPRESS MICRO)	Not Found	57-11-4
COLLOIDAL SILICON DIOXIDE (AEROSIL 200 PHARMA)	Not Found	7631-86-9

Section 4. First -aid measures

General

- **After inhalation:**
  Move to fresh air in case of accidental inhalation. assure fresh air breathing.
- **After skin contact:**
  Rinse skin with water/shower
- **After eye contact:**
  Rinse with water while holding the eyes wide open. Contact lenses should be removed.
- **After swallowing:**
  Rinse mouth out with water
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed-** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed-** No further relevant information available.

Overdose Treatment

Should overdose occur, basic steps to ensure the adequacy of an airway and the monitoring of cardiovascular and respiratory systems should be undertaken. Tizanidine is a lipid-soluble drug, which is slightly soluble in water and methanol. Therefore, dialysis is not likely to be an efficient method of removing drug from the body. In general, symptoms resolve within one to three days following discontinuation of tizanidine and administration of appropriate therapy. Due to the similar mechanism of action, symptoms and management of tizanidine overdose are similar to that following clonidine overdose. For the most recent information concerning the management of overdose, contact a poison control center.

Section 5. Fire -fighting measures	
	Extinguishing media · **Suitable extinguishing agents:** Use extinguishing media appropriate for surrounding fire. Extinguishing blanket. Carbon dioxide. Dry powder **Special hazards arising from the substance or mixture** Stable under normal conditions. · **Advice for firefighters** Small amounts: Use normal individual fire protective equipment. Large amounts: Not · **Protective equipment:** Hand protection: Gloves Skin and body protection: Lab coat Respiratory protection : Quarter mask (DIN EN 140)
Specific hazards arising from the chemical	No additional information available
Special protective equipment and precautions for firefighters	Use normal individual fire protective equipment
General fire hazards	No unusual fire or explosion hazards noted
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) [See USP Controlled Room Temperature]. Dispense in a tight container as defined in the USP with a child-resistant closure. • Keep container tightly closed • Dispense only in original container **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.
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 TIZANIDINE TABLETS USP 2 MG White to off-white, round, uncoated tablet debossed with '1' & '1' on either side of bisecting score on one side and debossed with '04' on the other side. Description of TIZANIDINE TABLETS USP 4 MG White to off-white, round, uncoated tablet with quadrisecting score on one side and debossed with '1105' on the other side.		
Solubility	Not available	**Odour**	Not available.
Boiling point	Not available.	**Melting Point**	Not available.
Evaporation rate	Not available.	**Vapour density**	Not available.
Reactivity in water	Not available.	**Vapour pressure**	Not available.
% Volatile by volume	Not available.	**Specific gravity**	Not available.

Section 10. Stability and Reactivity

Conditions to avoid	Contact with incompatible materials.
Stable	**Reactivity** The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Hazardous reactions	No dangerous reaction known under conditions of normal use.
Decomposition products	When heated to decomposition, emits dangerous fumes.
Incompatible materials	Strong Oxidizing agent

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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 specie formulation.
Ingestion	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.
Other	Not Available
Symptoms related to the physical, chemical and Toxicological characteristics	Not available
Information on toxicological effects	
Acute toxicity	Not available
Further information	Not available
Section 12. Ecological information	
	Poorly soluble in water. No data available on ecotoxicity.
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). In accordance with ADR / RID / IMDG / IATA / ADN
Section 15. Regulatory Information	
	Generic Medicine. Under Approval by USFDA
Section 16. Other information	
	None

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