Material Safety data sheet

ATENOLOL TABLETS USP

Strength: 25/50/100mg. **Pack Size:** 100 Tablets per bottle **Revision No.:** 00

EMERGENCY OVERVIEW

ATENOLOL TABLETS USP contain Atenolol and excipients generally considered to be non- toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

Section 1. Identification of the substance

Identification of the product

Product name:	Atenolol Tablets
Formula:	$C_{14}H_{22}N_2O_3$
Chemical Name:	benzeneacetamide, 4 -[2'-hydroxy-3'-[(1- methylethyl) amino] propoxy]-
Therapeutic Category	beta1-cardioselective adrenoreceptor-blocking agent

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

Section 2. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component :		
Atenolol, 25mg, 50mg and 100mg	Not Found	29122-68-7
Inactive Ingredients :		
Citric acid (anhydrous),	Not Found	77-92-9
Colloidal silicon dioxide,	Not Found	7621-86-9
Croscarmellose sodium,	Not Found	74811-65-7
Magnesium stearate,	Not Found	557-04-6
Microcrystalline cellulose (silicified),	Not Found	9004-34-6
Povidone.	Not Found	9003-39-8

Section 3. Health Hazards Information

Dose and Administration	**Hypertension and Acute Myocardial Infarction:** The usual oral adult dose of atenolol is 50 mg to 100 mg given as a single or divided doses. **Angina Pectoris :** The usual oral adult dose of atenolol is 50 mg to 200 mg given as a single or divided doses.
Adverse Effects	In addition, a variety of adverse effects have been reported with other beta-adrenergic blocking agents, and may be considered potential adverse effects of atenolol. **Hematologic :** Agranulocytosis. **Allergic :** Fever, combined with aching and sore throat, laryngospasm, and respiratory distress. **Central Nervous System :** Reversible mental depression progressing to catatonia; an acute reversible syndrome characterized by disorientation of time and place; short-term memory loss; emotional lability with slightly clouded sensorium; and, decreased performance on neuropsychometrics. **Gastrointestinal :** Mesenteric arterial thrombosis, ischemic colitis. **Other :** Erythematous rash. **Miscellaneous :** There have been reports of skin rashes and/or dry eyes associated with the use of beta-adrenergic blocking drugs. The reported incidence is small, and in most cases, the symptoms have cleared when treatment was withdrawn.
Over Dose Effect	Overdosage with atenolol has been reported with patients surviving acute doses as high as 5 g. One death was reported in a man who may have taken as much as 10 g acutely. The predominant symptoms reported following atenolol overdose are lethargy, disorder of respiratory drive, wheezing, sinus pause and bradycardia. Additionally, common effects are congestive heart failure, hypotension, bronchospasm and/or hypoglycemia.
Medical Conditions	Most adverse effects have been mild and transient. **Cardiovascular :**Bradycardia, Cold Extremities, Postural Hypotension, Leg Pain **Central Nervous System/Neuromuscular:**Dizziness, Vertigo, Lightheadedness, Tiredness Fatigue,Lethargy, Drowsiness, Depression, Dreaming **Gastrointestinal:**Diarrhea,Nausea **Respiratory :** Wheeziness,Dyspnea
Contraindications	Atenolol is contraindicated in sinus bradycardia, heart block greater than first-degree, cardiogenic shock, and overt cardiac Failure.Atenolol is contraindicated in those patients with a history of hypersensitivity to the atenolol or any of the drug product's components.
Pregnancy Comments	Atenolol can cause fetal harm when administered to a pregnant woman. Atenolol crosses the placental barrier and appears in cord blood. Administration of atenolol, starting in the second trimester of pregnancy, has been associated with the birth of infants that are small for gestational age. Neonates born to mothers who are receiving atenolol at parturition or breast-feeding may be at risk for hypoglycemia andbradycardia.
Pregnancy Category	**D**

Section 4. First aid measures

General	Remove from exposure. Remove contiminated Clothing. Person devloping serious hypersensitivity reaction must receive medical attention
Overdose Treatment	Treatment of overdose should be directed to the removal of any unabsorbed drug by induced emesis, gastric lavage, or administration of activated charcoal. Atenolol can be removed from the general circulation by hemodialysis. Other treatment modalities should be employed at the physician's discretion and which may be symptomatic and supportive.

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 mechanical equipment in contact with the dry material to dissipate the potential build up of static electricity.
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. Storage / Spill / Disposal Measures

Storage	Store at 20°-25°C (68°-77°F) Dispense in a tight, light-resistant container.
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.
Disposal	Dispose the waste in accordance with all applicable Federal, State and local laws.

Section 7. Exposure controls and 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.

Section 8. Physical and chemical properties

Appearance	Whit to Off white, round	**Odour**	Odourless
Solubility in water	No Data Available	**Melting Point**	No Data Available
Boiling point	No Data Available	**Vapour density**	No Data Available
Evaporation rate	No Data Available	**Evaporation rate**	No Data Available
Reactivity in water	No Data Available	**Specific gravity**	No Data Available
% Volatile by volume	No Data Available	**Vapour pressure**	No Data Available

Other information Atenolol (free base) has a molecular weight of 266. It is a relatively polar hydrophilic compound with a water solubility of 26.5mg/mL at 37°C and a log partition coefficient (octanol/water) of 0.23. It is freely soluble in 1N HCl (300 mg/mL at 25°C) and less soluble in chloroform (3 mg/mL at 25°C).

Section 9. Physical Hazards

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 10. Toxicological information

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

Target organ	Eye contact, Skin contact and inhalation is not great risk as this product is tablet.
other	Chronic studies employing oral atenolol performed in animals have revealed the occurrence of vacuolation of epithelial cells of Brunner's glands in the duodenum of both male and female dogs at all tested dose levels of atenolol (starting at 15 mg/kg/day or 7.5 times the maximum recommended human antihypertensive dose*) and increased incidence of atrial degeneration of hearts of male rats at 300 but not 150 mg atenolol/kg/day (150 and 75 times the maximum recommended human antihypertensive dose*, respectively). *Based on the maximum dose of 100 mg/day in a 50 kg patient.

Section 11. Ecological information

No data available on Ecotoxicity

Section 12. Other information

None

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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.