Safety Data Sheet
ATENOLOL TABLETS USP

Strength: 25/50/100mg.  Pack Size: 90/100/1000/2000/5000 & 10000 Tablets per bottle  Revision No.: 02

---

**EMERGENCY OVERVIEW**
Each Atenolol Tablet intended for oral administration contains 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

**Identification of the product**

**Product name:** Atenolol Tablets

**Formula:** C_{14}H_{22}N_{2}O_{3}

**Chemical Name:** Benzeneacetamide, 4- [2'-hydroxy-3' -[(1- methylethyl) amino] propoxy]-

---

**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**

Beta 1-cardioselective adrenoreceptor-blocking agent

**Restriction on Use / 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.
Section 2. Hazard (s) Identification

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 breastfeeding may be at risk for hypoglycemia and bradycardia.

Pregnancy Category

D

Section 3. Composition / information on ingredients

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

Section 4. First aid measures

| General | Remove from exposure. Remove contaminated clothing. Person developing 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

<table>
<thead>
<tr>
<th>Flash point</th>
<th>Not Found</th>
<th>Upper Flammable Limit:</th>
<th>Not Found</th>
</tr>
</thead>
<tbody>
<tr>
<td>Auto-Ignition</td>
<td>Not Found</td>
<td>Lower Flammable Limit:</td>
<td>Not Found</td>
</tr>
<tr>
<td>Temperature:</td>
<td></td>
<td>Fire and Explosion Hazard:</td>
<td>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.</td>
</tr>
<tr>
<td>Extinguishing Media</td>
<td>Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.</td>
<td>Fire Fighting Procedure:</td>
<td>As with all fires, evacuate personnel to a safe area. Fire fighter should use self-contained breathing equipment and protective clothing.</td>
</tr>
</tbody>
</table>

## 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). Dispense in a tight, light-resistant 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.
**Safety Data Sheet**
**ATENOLOL TABLETS USP**

**Strength:** 25/50/100mg.  
**Pack Size:** 90/100/1000/2000/5000 & 10000 Tablets per bottle  
**Revision No.:** 02

<table>
<thead>
<tr>
<th>Protective Clothing</th>
<th>Protective clothing is not normally necessary, however it is good practice to use apron.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Engineering Control</td>
<td>Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.</td>
</tr>
</tbody>
</table>

### Section 9. Physical and chemical properties

| Appearance | 25 mg are white to off-white, round uncoated tablets debossed with the logo of ‘Z’ on one side and ‘65’ on the other side.  
50 mg are white to off-white, round uncoated tablets debossed with ‘Z’, ‘66’ and bisect on one side and plain on the other side.  
100 mg are white to off-white, round uncoated tablets debossed with ‘Z’, ‘67’ on one side and plain on the other side. |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Odour</td>
<td>Odourless</td>
</tr>
</tbody>
</table>
| 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 |
| 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
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 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. |
Strength: 25/50/100mg.  Pack Size: 90/100/1000/2000/5000 & 10000 Tablets per bottle

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 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 12. Ecological information**
Do not allow product to enter drinking water supplies, waste water or soil

**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 076900

**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.