EMERGENCY OVERVIEW

Each Amlodipine Besylate Tablets intended for oral administration contain Amlodipine Besylate 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: Amlodipine Besylate Tablets

Formula: $C_{20}H_{25}CIN_{2}O_{5} \cdot C_{6}H_{6}O_{3}S$

Chemical Name: 3-Ethyl-5-methyl(±)-2-[(2-aminoethoxy) methyl]-4-(2-chlorophenyl)-1,4-dihydro-6-methyl-3,5-pyridinedicarboxylate, monobenzene sulphonate.

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 Long-acting calcium channel blocker.
Safety data sheet

AMLODIPINE BESYLATE TABLETS

Strength: 2.5\(\times\)10 mg. Pack Size: 90,100 and 500 Tablets per bottle

Revision No.: 02

| Restriction on Use / Contraindications: | Amlodipine is contraindicated in patients with known sensitivity to amlodipine. Rarely, patients, particularly those with severe obstructive coronary artery disease, have developed documented increased frequency, duration and/or severity of angina or acute myocardial infarction on starting calcium channel blocker therapy or at the time of dosage increase. |

### Section 2. Hazard(s) Identification

| Dose and Administration | The usual initial antihypertensive oral dose of amlodipine is 5 mg once daily with a maximum dose of 10 mg once daily. Small, fragile, or elderly individuals, or patients with hepatic insufficiency may be started on 2.5 mg once daily and this dose may be used when adding amlodipine to other antihypertensive therapy. |

| Adverse Effects | Most adverse reactions reported during therapy with amlodipine were of mild or moderate severity. |

**Cardiovascular:**
Arrhythmia, Bradycardia, chest pain, hypotension, peripheral ischemia, syncope, tachycardia, postural dizziness, postural hypotension, vasculitis.

**Central and Peripheral Nervous System:**
Hypoesthesia, neuropathy peripheral, paresthesia, tremor, vertigo.

**Gastrointestinal:**
Anorexia, constipation, dyspepsia, dysphagia, diarrhea, flatulence, pancreatitis, vomiting, gingival hyperplasia.

**General:**
Allergic reaction, asthenia, back pain, hot flushes, malaise, pain, rigors, weight gain, weight decrease.

**Musculoskeletal System:**
Arthralgia, arthrosis, muscle cramps, myalgia.

**Psychiatric:**
Sexual dysfunction (male and female), insomnia, nervousness, depression, abnormal dreams, anxiety, depersonalization.

**Respiratory System:**
Dyspnea, epistaxis.

**Skin and Appendages:**
Angioedema, erythema multiforme, pruritus, rash, rash erythematous, rash maculopapular.

**Special Senses:**
Abnormal vision, conjunctivitis, diplopia, eye pain, tinnitus.

**Urinary System:**
Micturition frequency, micturition disorder, nocturia.

**Autonomic Nervous System:**
Dry mouth, sweating increased.
Safety data sheet

**AMLODIPINE BESYLATE TABLETS**

**Strength:** 2.5/10 mg.  
**Pack Size:** 90,100 and 500 Tablets per bottle  
**Revision No.:** 02

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**Metabolic and Nutritional:**
Hyperglycemia, thirst.

**Hemopoietic:**
Leukopenia, purpura, thrombocytopenia.

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**Over Dose Effect**
Overdosage might be expected to cause excessive peripheral vasodilation with marked hypotension and possibly a reflex tachycardia.

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**Contraindications**
Amlodipine is contraindicated in patients with known sensitivity to amlodipine. Rarely, patients, particularly those with severe obstructive coronary artery disease, have developed documented increased frequency, duration and/or severity of angina or acute myocardial infarction on starting calcium channel blocker therapy or at the time of dosage increase.

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**Pregnancy Comments**
No evidence of teratogenicity or other embryo/fetal toxicity was found when pregnant rats and rabbits were treated orally with amlodipine maleate at doses up to 10 mg amlodipine/kg/day (respectively 8 times* and 23 times* the maximum recommended human dose of 10 mg on a mg/m² basis) during their respective periods of major organogenesis.

Amlodipine maleate has been shown to prolong both the gestation period and the duration of labor in rats at this dose. There are no adequate and well-controlled studies in pregnant women. Amlodipine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

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**Pregnancy Category**
C

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### 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>Amlodipine besylate</td>
<td>Not Found</td>
<td>111470-99-6</td>
</tr>
<tr>
<td>Colloidal silicon dioxide</td>
<td>Not Found</td>
<td>14808-60-7</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>Not Found</td>
<td>557-04-0</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>Not Found</td>
<td>9004-34-6</td>
</tr>
<tr>
<td>Sodium starch glycolate</td>
<td>Not Found</td>
<td>9063-38-1</td>
</tr>
</tbody>
</table>
Section 4. First-aid measures

General

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Overdose Treatment

If massive overdose should occur, active cardiac and respiratory monitoring should be instituted. Frequent blood pressure measurements are essential. Should hypotension occur, cardiovascular support including elevation of the extremities and the judicious administration of fluids should be initiated. If hypotension remains unresponsive to these conservative measures, administration of vasopressors (such as phenylephrine) should be considered with attention to circulating volume and urine output.

Intravenous calcium gluconate may help to reverse the effects of calcium entry blockade. As amlodipine is highly protein bound, hemodialysis is not likely to be of benefit.

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 Temperature:</td>
<td>Not Found</td>
<td>Lower Flammable Limit:</td>
<td>Not Found</td>
</tr>
</tbody>
</table>
Safety data sheet

AMLODIPINE BESYALTE TABLETS

Strength: 2.5, 5, 10 mg.

Pack Size: 90, 100 and 500 Tablets per bottle

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 buildup 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. Accidental Release Measure

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°C to 25°C (86° to 77°C F) protect from light.

Incompatibility
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.
Safety data sheet

AMLODIPINE BESYLA TE TABLETS

Strength: 2.5\(\text{mg}\), 5\(\text{mg}\), 10\(\text{mg}\) Pack Size: 90,100 and 500 Tablets per bottle

Revision No.: 02

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**

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Appearance</strong></td>
<td>Amlodipine Besylate Tablets, 2.5 mg are white to off-white, round, flat, radial-edged tablets, debossed with ‘Z’ on one side and ‘7’ on the other side.</td>
</tr>
<tr>
<td></td>
<td>Amlodipine Besylate Tablets, 5 mg are white to off-white, round, flat, radial-edged tablets, debossed with ‘Z’, ‘3’ on one side and plain on the other side.</td>
</tr>
<tr>
<td></td>
<td>Amlodipine Besylate Tablets, 10 mg are white to off-white, round, flat, radial-edged tablets, debossed with ‘Z’, ‘5’ on one side and plain on the other side.</td>
</tr>
<tr>
<td><strong>Odour</strong></td>
<td>Odourless</td>
</tr>
<tr>
<td><strong>Solubility in water</strong></td>
<td>No Data Available</td>
</tr>
<tr>
<td><strong>Melting Point</strong></td>
<td>Vapour density</td>
</tr>
<tr>
<td><strong>Boiling point</strong></td>
<td>No Data Available</td>
</tr>
<tr>
<td><strong>Evaporation rate</strong></td>
<td>Vapour pressure</td>
</tr>
<tr>
<td><strong>Evaporation rate</strong></td>
<td>No Data Available</td>
</tr>
<tr>
<td><strong>Reactivity in water</strong></td>
<td>No Data Available</td>
</tr>
<tr>
<td><strong>% Volatile by volume</strong></td>
<td>No Data Available</td>
</tr>
<tr>
<td><strong>Other information</strong></td>
<td>Amlodipine besylate is a white or almost white crystalline powder with a molecular weight of 567.1. It is slightly soluble in water and sparingly soluble in ethanol.</td>
</tr>
</tbody>
</table>

**Section 10. Stability and Reactivity**

<table>
<thead>
<tr>
<th>Condition to avoid</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Avoid</strong></td>
<td>Avoid exposure to extreme heat, light and moisture.</td>
</tr>
<tr>
<td><strong>Stable</strong></td>
<td>Stable under normal ambient and anticipated storage and handling conditions.</td>
</tr>
<tr>
<td><strong>Decomposition</strong></td>
<td>No Data Available</td>
</tr>
<tr>
<td><strong>Hazardous</strong></td>
<td>No data available.</td>
</tr>
<tr>
<td><strong>Products</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Incompatibilities</strong></td>
<td>No data available.</td>
</tr>
</tbody>
</table>
# Safety data sheet

**AMLODIPINE BESYLATE TABLETS**

**Strength:** 2.5\(\text{mg}\), 5\(\text{mg}\), 10\(\text{mg}\)  
**Pack Size:** 90, 100 and 500 Tablets per bottle

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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.

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

### Other
Not Applicable

## Section 12. Ecological information
No data available on Ecotoxicity. 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 078226.

## Section 16. Other information
None

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

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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.