

# Material Safety data sheet

## AMLODIPINE BESYLATE TABLETS

Strength: 2.5 mg.

Strength: 5.0 mg.

Strength: 10 mg.

Pack Size: 90,100 and 500 Tablets per bottle

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Revision No.: 00

### EMERGENCY OVERVIEW

AMLODIPINE BESYLATE TABLETS 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 of the substance

### Identification of the product

<b>Product name:</b>	Amlodipine Besylate Tablets
<b>Formula:</b>	$C_{20}H_{25}ClN_2O_5 \cdot C_6H_6O_3S$ ,
<b>Chemical Name:</b>	3-Ethyl-5-methyl ( $\pm$ )-2-[(2-aminoethoxy) methyl]-4-(2-chlorophenyl)-1,4-dihydro-6-methyl-3,5-pyridinedicarboxylate, monobenzenesulphonate
<b>Therapeutic Category</b>	a long-acting calcium channel blocker.

### Manufacturer / supplier identification

<b>Company:</b>	<b>Cadila Healthcare Ltd. Ahmedabad, India</b>
<b>Contact for information:</b>	Tel.: +91 79 6868100 Fax: +91 79 3750319
<b>Emergency telephone No.</b>	Tel.: +91 79 6868100

## Section 2. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Amlodipine besylate	Not Found	111470-99-6
Colloidal silicon dioxide	Not Found	14808-60-7
Magnesium stearate	Not Found	557-04-0
Microcrystalline cellulose	Not Found	9004-34-6
Sodium starch glycolate.	Not Found	9063-38-1

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### Section 3. Health Hazards Information

#### 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.

##### Metabolic and Nutritional:

Hyperglycemia, thirst.

##### Hemopoietic:

Leukopenia, purpura, thrombocytopenia.

#### 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.

### 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/m<sup>2</sup> 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.

### Pregnancy Category

C

## Section 4. First aid measures

### General

Remove from exposure. Remove contaminated Clothing. Person developing serious hypersensitivity reaction must receive medical attention.

### 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.

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### Section 5. Fire – fighting measures

<b>Flash point</b>	Not Found	<b>Upper Flammable Limit:</b>	Not Found
<b>Auto-Ignition Temperature:</b>	Not Found	<b>Lower Flammable Limit:</b>	Not Found
<b>Extinguishing Media</b>	Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.	<b>Fire and Explosion Hazard</b>	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.
<b>Fire Fighting Procedure</b>	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° to 25°C (68° to 77°F). Protect from light.
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.

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### Section 8. Physical and chemical properties

<b>Appearance</b>	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.		
	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.		
	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.		
<b>Odour</b>	Odourless	<b>Melting Point</b>	No Data Available
<b>Solubility in water</b>	No Data Available	<b>Vapour density</b>	No Data Available
<b>Boiling point</b>	No Data Available	<b>Evaporation rate</b>	No Data Available
<b>Evaporation rate</b>	No Data Available	<b>Specific gravity</b>	No Data Available
<b>Reactivity in water</b>	No Data Available	<b>Vapour pressure</b>	No Data Available
<b>% Volatile by volume</b>	No Data Available		
<b>Other information</b>	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.		

### Section 9. Physical Hazards

<b>Condition to avoid</b>	Avoid exposure to extreme heat, light and moisture.	<b>Stable</b>	Stable under normal ambient and anticipated storage and handling conditions.
<b>Decomposition Products</b>	No Data Available	<b>Hazardous Reaction</b>	No data available.
<b>Incompatibilities</b>	No data available.		

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### Section 10. Toxicological information

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      Refer contraindication and adverse effect.

other              Not Available

### Section 11. Ecological information

No data available on Ecotoxicity

### Section 12. Other information

None

Date of issue:      04/07/07

Supersedes edition of: New Addition

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.