

SAFETY DATA SHEET

Amlodipine Besylate Tablets, USP

1. IDENTIFICATION

Manufacturer:

InvaGen Pharmaceuticals Inc
7, Oser Avenue
Hauppauge, NY 11788

Emergency Phone:

1-631-231-3233

Common Name: Amlodipine Besylate Tablets

Chemical Family: Calcium Channel Blocker

Synonym(s): Amlodipine benzenesulfonate, Amlodipine besilate

Chemical Name: 3,5-Pyridinecarboxylic acid,2-[(2-aminoethoxy)methyl]-4-(2-chlorophenyl)-1,4-dihydro-6-methyl, 3-ethyl-5-methyl ester, (+/-)-, monobenzenesulfonate

Trade Name(s): Amlodipine Besylate Tablets, USP

Therapeutic Category: Antihypertensive, Antianginal

Molecular formula: C₂₀H₂₅ClN₂O₅•C₆H₆O₃S **Molecular Weight:** 567.1

2. HAZARDS IDENTIFICATION

Not considered hazardous when handled under normal conditions.

EMERGENCY OVERVIEW

Caution Statement: Each Amlodipine Tablets intended for oral administration contains Amlodipine Besylate and excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

Routes of Entry: Oral

Effects of Overexposure: Tablets are intended for human consumption under guidance of a physician. Intact tablets are not considered hazardous under normal handling procedures.

Medical conditions Aggravated by Long Term Exposure:

No Data Available.

Carcinogenicity: Amlodipine Besylate - Not listed by IARC, NTP and OSHA.

3.COMPOSITION / INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>CAS #</u>	<u>Concentration %</u>		
		2.5 mg	5 mg	10 mg
Amlodipine Besylate, USP	11470-99-6	≈3.86 %	≈3.86 %	≈3.86 %
Excipients	NA	≈96.14 %	≈96.14 %	≈96.14 %

Contains no hazardous components (one percent or greater) or carcinogens (one-tenth percent or greater) not listed above.

* All Concentrations are percent by weight.

4. FIRST AID MEASURES

Inhalation: Move in to fresh air and keep at rest. For breathing difficulties, Oxygen may be necessary. Get medical attention. If breathing stops, provide artificial respiration.

Skin Contact: Wash skin thoroughly with soap and water. Get medical attention if irritation persists after washing. Remove contaminated clothing and shoes. Wash contaminated clothing before reuse. Destroy or thoroughly clean contaminated shoes.

Eye Contact: Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

Ingestion: Do not induce vomiting unless directed to do so by medical personnel. Never give liquid to an unconscious person. Get medical attention.

Notes to the Physician:

Amlodipine Besylate, USP is a calcium channel blocker and may be used alone or in combination with other antihypertensive and antianginal agents.

Overdose Treatment:

Overdosage might be expected to cause excessive peripheral vasodilation with marked hypotension and possibly a reflex tachycardia. In humans, experience with intentional overdosage of amlodipine is limited.

5.FIRE-FIGHTING MEASURES

Extinguishing Media: Water spray, CO₂, dry chemical or alcohol resistant foam.

Unusual Fire & Explosion Hazards: Emits toxic fumes under fire conditions.

Special Fire Fighting Procedures: Self-Contained breathing apparatus and full protective clothing must be worn in case of fire.

Protective Measures: Prevent runoff from fire control or dilution from entering streams, sewers, or drinking water supply.

6.ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment. Immediately contact emergency personnel. Keep unnecessary personnel away. Follow all firefighting procedures.

Environmental precautions: Do not release in to the environment.

Spill Cleanup methods: Use a vacuum cleaner. If not possible, moisten dust with water before it is collected with shovel, broom or the like. Collect in containers and seal securely. For waste disposal, see section 13 of the SDS.

7.HANDLING AND STORAGE

Handling: Do not breathe dust. Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling.

Storage: Keep container tightly closed in a cool, well-ventilated place. Keep away from heat and direct sun light.

8.EXPOSURE CONTROLS / PERSONAL PROTECTION

Compressed tablets are not considered hazardous under normal handling procedures and protective equipment is not required. The following are recommended for manufacturing or other situations where exposure to the powder may occur.

Protective Measures: Minimize open handling. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas.

Respiratory Protection: Use a NIOSH approved respirator or an alternate approved dust mask should be used.

Hand Protection: Chemical resistant gloves.

Eye Protection: Wear safety glasses with side shields (or goggles). If the work environment or activity involves dusty conditions, mist or aerosols, wear the appropriate goggles. Wear a face shield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and Body Protection: Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

Hygiene Measures: Wash skin thoroughly with soap and water.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical Properties:

Physical State: Solid

Form: Tablets

Appearance:

2.5 mg Tablets: White, round, flat faced beveled edged tablets de-bossed with “IG” on one side and “237” on the other.

5 mg Tablets: White, round, flat faced beveled edged tablets de-bossed with “IG” on one side and “238” on the other.

10 mg Tablets: White, round, flat faced beveled edged tablets de-bossed with “IG” on one side and “239” on the other.

10. STABILITY AND REACTIVITY

Possibility of hazardous reactions: Stable under ordinary conditions of use and storage.

Conditions to avoid: Excessive heat & Moisture.

Incompatible materials: Strong oxidizers, Strong Bases and Strong Acids.

Hazardous Decomposition products: Thermal decomposition or combustion may liberate irritating gases or vapors.

11.TOXICOLOGICAL INFORMATION

General information: The information presented below pertains to the individual ingredients (Amlodipine Besylate, USP), and not to the mixture(s) or final formulations.

Inhalation: No data available.

Ingestion: May be harmful if swallowed. (Amlodipine Besylate, USP)

Skin Corrosion/ irritation: No data available.

Serious eye damage/eye irritation: May cause eye irritation. (Amlodipine Besylate, USP)

Respiratory sensitizer/Skin sensitizer: May cause respiratory tract irritation. (Amlodipine Besylate, USP)

Carcinogenesis:

Rats and mice treated with amlodipine maleate in the diet for up to two years, at concentrations calculated to provide daily dosage levels of 0.5 mg, 1.25 mg, and 2.5 mg amlodipine mg/kg/day, showed no evidence of a carcinogenic effect of the drug. For the mouse, the highest dose was, on a mg/m² basis, similar to the maximum recommended human dose of 10 mg amlodipine/day.³ For the rat, the highest dose was, on a mg/m² basis, about twice the maximum recommended human dose.

Mutagenesis:

3 Mutagenicity studies conducted with amlodipine maleate revealed no drug related effects at either the gene or chromosome level.

Impairment of Fertility:

There was no effect on the fertility of rats treated orally with amlodipine maleate (males for 64 days and females for 14 days prior to mating) at doses up to 10 mg amlodipine/kg/day (8 times the maximum recommended human dose³ of 10 mg/day on a mg/ m² basis). ³ Based on patient weight of 50 kg

Other information:

Amlodipine Besylate tablets have been evaluated for safety in more than 11,000 patients in U.S. and foreign clinical trials. In general, treatment with amlodipine besylate tablets was well-tolerated at doses up to 10 mg daily. Most adverse reactions reported during therapy with amlodipine besylate tablets were of mild or moderate severity. In controlled clinical trials directly comparing amlodipine besylate tablets (N=1730) at doses up to 10

mg to placebo (N=1250), discontinuation of amlodipine besylate tablets because of adverse reactions was required in only about 1.5% of patients and was not significantly different from placebo (about 1%).

12.ECOLOGICAL INFORMATION

General information: The information presented below pertains to the individual ingredients (Amlodipine Besylate), and not to the mixture(s) or final formulations.

Ecotoxicity Effects:

Acute toxicity to Fish: No data available.

Acute toxicity to Aquatic Invertebrates: No data available.

Toxicity to Aquatic Plants: No data available.

Bioaccumulation: No data available.

Mobility: No data available.

13.DISPOSAL CONSIDERATIONS

Waste Disposal: Dispose of waste must be in accordance with all applicable Federal, State and local laws.

Measures for Avoidance and Recovery: Incineration is the most effective method of disposal in most instances. Do not allow runoff to sewer, waterway or ground. Operations that involve the crushing or shredding of waste materials or returned goods should take into account recommended exposure limits where they exist.

14.TRANSPORT INFORMATION

DOT: Not Regulated

IMDG: Not regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

15.REGULATORY INFORMATION

Stated regulatory information chosen primarily for possible usage of InvaGen Pharmaceutical, Inc. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

CERLA Hazardous Substance List (40 CFR 302.4): None

TSCA : None

SARA Title III
Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A): None

Section 313 Toxic Release Inventory (40 CFR 372): None

16.OTHER INFORMATION

SDS Sections Revised:

Revision 01: Sections 1 to 16 contain revisions to comply with 29 CFR 1910.1200(g) and Appendix D.

GLOSSARY:

SDS	Safety Data Sheet
NA	Not Applicable
CAS Number	Chemical Abstract Service Registry Number
NTP	National Toxicology Program
NIOSH	National Institute for Occupational Safety and Health
DOT	Department of Transportation
IMDG	International Maritime Dangerous Goods Code
ICAO	International Civil Aviation Organization
IATA	International Air Transport Association
IMO	International Maritime Organization
TSCA	Toxic Substances Control Act
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
SARA	Superfund Amendments and Reauthorization Act
OSHA	Occupational Safety and Health Administration

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