

LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Product Name	Azilsartan Medoxomil Tablets
Manufacturer	Lupin Limited Nagpur 441 108 India
Manufactured for	Lupin Pharmaceuticals, Inc. Naples, FL 34108 United States Tel. 001-410-576-2000 Fax. 001-410-576-2221

Section 2: Hazard(s) Identification

Fire & Explosion	Expected to be non-combustible.
Health	Please read the product information leaflet before use. May cause respiratory irritation.

Section 3: Composition/Information on Ingredients

Ingredients	CAS
Azilsartan Medoxomil	863031-21-4
Mannitol USP	69-65-8
Hydroxypropyl Cellulose NF	9004-64-2
Acetone NF	67-64-1
Purified Water	7732-18-5
Croscarmellose Sodium NF	74811-65-7
Vanillin	121-33-5
Microcrystalline Cellulose NF	9004-34-6
Magnesium Stearate NF	557-04-0

* The exact percentage composition of this mixture has been withheld as a trade secret.

Section 4: First-Aid Measures

Ingestion	If swallowed, do not induce vomiting. Observe the patient carefully. Never give liquid to a person showing signs of being sleepy or with reduced awareness. Seek medical advice.
Inhalation	Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance.
Skin Contact	Wash all exposed areas of skin with plenty of soap and water. Obtain medical attention if skin reaction occurs.
Eye Contact	Flush eyes with plenty of water. Get medical attention.

Section 5: Fire-Fighting Measures

Extinguishing Media	Use extinguishing media suitable for the surrounding area.
Special Firefighting Procedures	Wear self contained breathing apparatus and protective clothing, gloves in the event of a fire.
Hazardous Combustion Products	Hazardous combustion or decomposition products are expected when the product is exposed to fire

Section 6: Accidental Release Measures

Personal Precautions, Protective Equipment.	Wear suitable protective clothing, gloves and eye/face protection.
Environmental Precautions	Avoid discharge into drains, water courses or onto the ground.

Section 7: Handling and Storage

Handling	No special control measures are required for the normal handling of this product. Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid prolonged or repeated exposure. Keep away from sources of ignition.
Storage	Store at 25°C (68°F to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Keep container tightly closed. Protect from moisture and light. Do not repackage; dispense and store in original container.

Section 8: Exposure Controls/Personal Protection

Personal Protection	Avoid all unnecessary exposure. Wear appropriate clothing to avoid skin contact. Wash your hands and arms thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice
Appropriate engineering controls	Work must be done with effective mechanical ventilation.

Section 9: Physical and Chemical Properties

How Supplied	Azilsartan medoxomil tablets, 40 mg are white to off-white round tablets debossed "J4" on one side and "L" on other side Bottle of 30 tablets: NDC 70748-236-06 Azilsartan medoxomil tablets, 80 mg are white to off-white round tablets debossed "J5" on one side and "L" on other side. Bottle of 30 tablets: NDC 70748-237-06.
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Section 10: Stability and Reactivity

Stable under recommended storage conditions.

Section 11: Toxicological Information

Carcinogenic categories	NO
Mutagenicity	NO
Reproductivity:	NO
Respiratory or Skin Sensitization	NO
Skin Irritation/Corrosion NO	NO

Section 12: Ecological Information

No relevant studies identified.

Section 13: Disposal Considerations

Follow all federal, state, and local environmental regulations.

Section 14: Transport Information

IATA/ICAO - Not Regulated

IATA Proper shipping Name	:	N/A
IATA UN/ID No	:	N/A
IATA Hazard Class	:	N/A
IATA Packaging Group	:	N/A
IATA Label	:	N/A

IMDG - Not Regulated

IMDG Proper shipping Name	:	N/A
IMDG UN/ID No	:	N/A
IMDG Hazard Class	:	N/A
IMDG Flash Point	:	N/A
IMDG Label	:	N/A

DOT - Not Regulated

DOT Proper shipping Name	:	N/A
DOT UN/ID No	:	N/A
DOT Hazard Class	:	N/A
DOT Flash Point	:	N/A
DOT Packing Group	:	N/A
DOT Label	:	N/A

Section 15: Regulatory Information

This Section Contains Information relevant to compliance with other Federal and/or state laws.

Section 16: Other Information

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Lupin shall not be held liable for any damage resulting from handling or from contact with the above product. Lupin reserves the right to revise this MSDS.