Safety Data Sheet
AZATHIOPRINE TABLETS, USP

Strength: 50mg. **Pack Size:** 100/500 Tablets per bottle **Revision No.:** 02

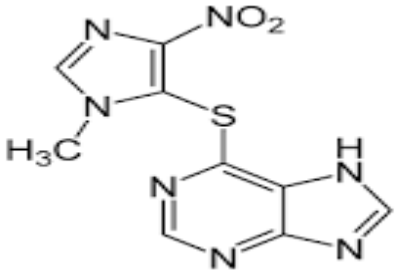
EMERGENCY OVERVIEW

Each Azathioprine Tablet, USP intended for oral administration contains Azathioprine 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:	**Azathioprine Tablets, USP**
Formula:	$C_9H_7N_7O_2$
Chemical Name:	6-[(1-Methyl-4-nitro-1H-imidazol-5-yl) sulfanyl]-1H-purine.



Manufacturer / supplier identification

Company:	**Cadila Healthcare Ltd. Ahmedabad, India**
Address:	Sarkhej – Bavla. N.H. 8A, Moraiya. Tal. Sanand. Dist. Ahmedabad – 382210. State: Gujarat. India
Contact for information:	Tel.: +91 79 6868100 Fax: +91 79 3750319
Emergency Telephone No.	Tel.: +91 79 6868100
Recommended use / Therapeutic Category	Immunosuppressive Antimetabolite.
Restriction on Use / Contraindications:	Azathioprine tablets should not be given to patients who have shown hypersensitivity to the drug. Azathioprine tablets should not be used for treating rheumatoid arthritis in pregnant women. Patients with rheumatoid arthritis previously treated with alkylating agents (cyclophosphamide, chlorambucil,

melphalan, or others) may have a prohibitive risk of neoplasia if treated with azathioprine tablets. Azathioprine tablets are mutagenic in animals and humans, carcinogenic in animals, and may increase the patient's risk of neoplasia. Renal transplant patients are known to have an increased risk of malignancy, predominantly skin cancer and reticulum cell or lymphomatous tumors.

Section 2. Hazard(s) Information

Dose and Administration

Renal Homotransplantation

The dose of azathioprine tablets required to prevent rejection and minimize toxicity will vary with individual patients; this necessitates careful management. The initial dose is usually 3 to 5 mg/kg daily, beginning at the time of transplant.

Rheumatoid Arthritis

Azathioprine tablets are usually given on a daily basis. The initial dose should be approximately 1.0 mg/kg (50 to 100 mg) given as a single dose or on a twice-daily schedule.

Adverse Effects

Leukopenia and/or thrombocytopenia are dose-dependent and may occur late in the course of therapy with azathioprine tablets. Nausea and vomiting may occur within the first few months of therapy with azathioprine tabletsAdditional side effects of low frequency have been reported. These include skin rashes, alopecia, fever, arthralgias, diarrhea, steatorrhea, negative nitrogen balance, and reversible interstitial pneumonitis.

Over Dose Effect

The oral LD50s for single doses of azathioprine tablets in mice and rats are 2500 mg/kg and 400 mg/kg, respectively. Very large doses of this antimetabolite may lead to marrow hypoplasia, bleeding, infection, and death. About 30% of azathioprine is bound to serum proteins, but approximately 45% is removed during an 8-hour hemodialysis.24 A single case has been reported of a renal transplant patient who ingested a single dose of 7500 mg azathioprine. The immediate toxic reactions were nausea, vomiting, and diarrhea, followed by mild leukopenia and mild abnormalities in liver function. The white blood cell count, SGOT, and bilirubin returned to normal 6 days after the overdose.

Medical Conditions

General

Malignancy Patients receiving immunosuppressants, including azathioprine, are at increased risk of developing lymphoma and other malignancies, particularly of the skin. Physicians should inform patients of the risk of malignancy with azathioprine. As usual for patients with increased risk for skin cancer, exposure to sunlight and

ultraviolet light should be limited by wearing protective clothing and using a sunscreen with a high protection factor.

Contraindications

Azathioprine tablets should not be given to patients who have shown hypersensitivity to the drug. Azathioprine tablets should not be used for treating rheumatoid arthritis in pregnant women. Patients with rheumatoid arthritis previously treated with alkylating agents (cyclophosphamide, chlorambucil, melphalan, or others) may have a prohibitive risk of neoplasia if treated with azathioprine tablets.

Azathioprine tablets are mutagenic in animals and humans, carcinogenic in animals, and may increase the patient's risk of neoplasia. Renal transplant patients are known to have an increased risk of malignancy, predominantly skin cancer and reticulum cell or lymphomatous tumors.

Pregnancy Category

Azathioprine tablets can cause fetal harm when administered to a pregnant woman.

Azathioprine tablets should not be given during pregnancy without careful weighing of risk versus benefit. Whenever possible, use of azathioprine tablets in pregnant patients should be avoided.

Pregnancy Category **D**

Section 3. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component :		
Azathioprine	Not Found	446-86-6
Inactive Ingredients :		
Croscarmellose sodium	Not Found	74811-65-7
Lactose monohydrate	Not Found	67392-87-4
Magnesium stearate	Not Found	557-04-0
Povidone	Not Found	9003-39-8
Starch	Not Found	119-58-4

Section 4. First - aid measures

General	Remove from exposure. Remove contaminated Clothing. Person developing serious hypersensitivity reaction must receive medical attention
Overdose Treatment	Reduction of azathioprine dosage and/or use of other drugs should be considered.

Section 5. Fire - fighting measures

Flash point	Not Found	**Upper Flammable Limit:**	Not Found
Auto-Ignition Temperature:	Not Found	**Lower Flammable Limit:**	Not Found
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 build-up 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 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) in a dry place and protect from light**.** Dispense in a tight, light-resistant container.
Incompatibilities:	Reactive with oxidizing agents, alkalis.

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.
Engineering Control	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.

Section 9. Physical and chemical properties

Appearance Azathioprine Tablets USP, 50 mg are yellow, round, flat, beveled edge tablets with bisect on one side; one side of the bisect is debossed with logo of "ZC" and other side is debossed with "59" and other side is plain

Solubility in water	No Data Available	**Odour**	Odourless
Boiling point	No Data Available	**Melting Point**	No Data Available
Evaporation rate	No Data Available	**Vapour density**	No Data Available
Reactivity in water	No Data Available	**Evaporation rate**	No Data Available
% Volatile by volume	No Data Available	**Specific gravity**	No Data Available
		Vapour pressure	No Data Available

Other information Azathioprine is a pale yellow, odorless powder. It is insoluble in water, soluble in Dilute solutions of alkali hydroxides, sparingly soluble in dilute mineral acids, very slightly soluble in alcohol and in chloroform.

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.

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Decomposition Products	No Data Available	**Hazardous Reaction**	No data available.

Incompatibilities: Reactive with oxidizing agents, alkalis.

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 Azathioprine tablets are teratogenic in rabbits and mice when Given in doses equivalent to the human dose (5 mg/kg daily). Abnormalities included skeletal malformations and visceral anomalies.

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 077621

Section 16. Other information

None

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