Safety Data Sheet **Revision No.:** 01
Acetazolamide Tablets USP, Strength: 125mg/250mg
Pack Size: 100 Tablets per bottle

EMERGENCY OVERVIEW
Each Acetazolamide Tablets USP intended for oral administration contains Acetazolamide and excipients generally considered non- toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

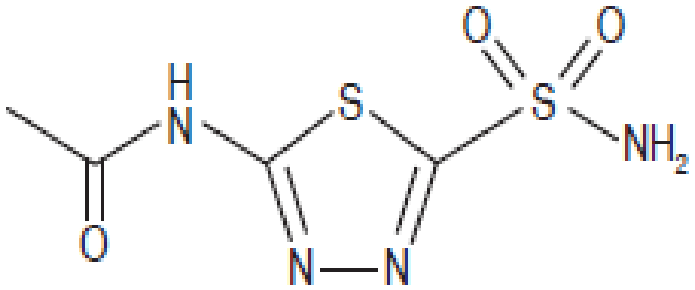
Section 1. IDENTIFICATION

Identification of the product

Product Name: Acetazolamide Tablets USP

Formula: $C_4H_6N_4O_3S_2$

Chemical Name: N-(5-Sulfamoyl-1,3,4-thiadiazol-2-yl)-acetamide



Manufacturer / Supplier identification

Company:	**Zydus Lifesciences Limited (Formerly known as Cadila Healthcare Limited Baddi, India)**
Address:	**Zydus Lifesciences Limited**, Swaraj Majra, Judi Kalan, Post - Baddi, Tehsil - Nalagarh, District - Solan, Himachal Pradesh 173205.
Contact for information:	Tel: +91-1795-246841 Fax: +91-1795-246842
Emergency Telephone No.	Tel: +91-1795-246841
Recommended use / Therapeutic Category	For adjunctive treatment of: edema due to congestive heart failure; drug-induced edema; centrencephalic epilepsies (petit mal, unlocalized seizures); chronic simple (open-angle) glaucoma, secondary glaucoma, and preoperatively in acute angle-closure glaucoma where delay of surgery is desired in order to lower intraocular pressure.
Restriction on Use / Contraindications:	It is contraindicated in patients with cirrhosis because of the risk of development of hepatic encephalopathy.

Section 2. HAZARD(S) IDENTIFICATION

Dose and Administration

Glaucoma	Acetazolamide should be used as an adjunct to the usual therapy. The dosage employed in the treatment of chronic simple (open-angle) glaucoma ranges from 250 mg to 1 g of acetazolamide per 24 hours, usually in divided doses for amounts over 250 mg.
Congestive Heart Failure	For diuresis in congestive heart failure, the starting dose is usually 250 to 375 mg once daily in the morning (5 mg/kg). If, after an initial response, the patient fails to continue to lose edema fluid, do not increase the dose but allow for kidney recovery by skipping medication for a day.
Epilepsy	The suggested total daily dose is 8 to 30 mg per kg in divided doses. Although some patients respond to a low dose, the optimum range appears to be from 375 to 1000 mg daily. However, some investigators feel that daily doses in excess of 1 g do not produce any better results than a 1 g dose.
Drug-Induced Edema	Recommended dosage is 250 to 375 mg of acetazolamide once a day for one or two days, alternating with a day of rest.
Acute Mountain Sickness	Dosage is 500 mg to 1000 mg daily, in divided doses. In circumstances of rapid ascent, such as in rescue or military operations, the higher dose level of 1000 mg is recommended. It is preferable to initiate dosing 24 to 48 hours before ascent and to continue for 48 hours while at high altitude, or longer as necessary to control symptoms.
Adverse Effects	Adverse reactions, occurring most often early in therapy, include paresthesias, particularly a "tingling" feeling in the extremities, hearing dysfunction or tinnitus, loss of appetite, taste alteration and gastrointestinal disturbances such as nausea, vomiting and diarrhea, polyuria, and occasional instances of drowsiness and confusion.
Over Dose Effect	No data are available regarding acetazolamide overdosage in humans as no cases of acute poisoning with this drug have been reported. Animal data suggest that acetazolamide is remarkably nontoxic. No specific

antidote is known. Treatment should be symptomatic and supportive.

Contraindications Acetazolamide therapy is contraindicated in situations in which sodium and/or potassium blood serum levels are depressed, in cases of marked kidney and liver disease or dysfunction, in suprarenal gland failure, and in hyperchloremic acidosis.

Pregnancy Comments Pregnancy Category C
Acetazolamide, administered orally or parenterally, has been shown to be teratogenic (defects of the limbs) in mice, rats, hamsters and rabbits. There are no adequate and well-controlled studies in pregnant women. Acetazolamide should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus.

Section 3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	Exposure Limit	CAS No.
Principle Component:		
Acetazolamide	Not Found	59-66-5
Inactive Ingredients:		
Lactose monohydrate	Not Found	64044-51-5
Sodium Starch Glycolate	Not Found	9063-38-1
Corn Starch	Not Found	9005-25-8
Povidone	Not Found	9003-39-8
Magnesium Stearate	Not Found	557-04-0

Section 4. FIRST-AID MEASURES

Inhalation Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.

Skin Contact Immediately wash skin with soap and plenty of water. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.

Eye Contact Hold eyelids apart and flush eyes with plenty of water. Have eyes examined and tested by medical personnel.

Ingestion	Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. Do NOT induce vomiting unless directed to do so by medical personnel.

Section 5. FIRST FIGHTING MEASURES

Flash Point	Not available
Extinguishing Media	Use alcohol-resistant foam, carbon dioxide, water, or dry chemical spray. Use water spray to cool fire-exposed containers.
Unusual Fire and Explosion Hazards	No unusual fire or explosion hazards noted.
Fire Fighting Instructions	Wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes

Section 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.
Methods and materials for containment and cleaning up	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

Section 7. HANDLING AND STORAGE

Storage	Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].
Precautions for safe handling	Avoid prolonged exposure. Avoid contact with eyes. Avoid release to environment. Use with adequate ventilation. When handling, use proper personal protective equipment. Wash thoroughly after handling. Keep container tightly closed when not in in use.

Section 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Respiratory Protection	Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. However, no personal respiratory protective equipment normally required.
Skin Protection	For prolonged or repeated skin contact use suitable protective gloves.
Eye/Face Protection	If contact is likely, safety glasses with side shields are recommended.
Protective Clothing	Protective clothing is not normally necessary; however, it is good practice to use apron.
Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	General ventilation normally adequate.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.
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

Physical state	Solid
Color	White to off-white
Odor	No unpleasant odor.
Pure/Mixture	Mixture

Section 10. STABILITY AND REACTIVITY

Stability	Normally stable but formation of toxic gases is possible during heating or in case of fire.
Incompatibility materials to avoid	Strong Oxidizing agents
Polymerization	Will not occur

Section 11. TOXILOGICAL INFORMATION

Ingestion	Toxic if Swallowed.
Inhalation	Due to lack of data, the classification is not possible.
Skin contact	Based on available data, the classification criteria are not met.
Eye contact	Causes eye irritation.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals to evaluate the carcinogenic potential of acetazolamide have not been conducted. In a bacterial mutagenicity assay, acetazolamide was not mutagenic when evaluated with and without metabolic activation.

The drug had no effect on fertility when administered in the diet to male and female rats at a daily intake of up to 4 times the recommended human dose of 1000 mg in a 50 kg individual.

Section 12. ECOLOGICAL INFORMATION

Do not allow product to enter drinking water supplies, wastewater or soil.

Section 13. DISPOSAL CONSIDERATION

Disposal Recommendations 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, ANDA Number 211069

Section 16. OTHER INFORMATION

Additional Information

NFPA Rating: These ratings are based on NFPA code 704 and are intended for use by emergency personnel to determine the immediate hazards of a material

Health……..2

Fire……..0

Reactivity…0

Date of issue: July 19, 2023 **Supersedes edition:** 00

The information presented in the safety data sheet is, to the best our knowledge, accurate and reliable. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.