Material Safety data sheet

ACETAZOLAMIDE ER CAPSULES

Strength: 500 mg. **Pack Size:** 100/1000 Capsules per bottle **Revision No.:** 00

EMERGENCY OVERVIEW

ACETAZOLAMIDE ER CAPSULE contains Acetazolamide 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

Product name: Acetazolamide ER Capsules

Formula: $C_4H_6N_4O_3S_2$

Chemical Name: Acetamide, N-(5-sulfamoyl-1 ,3,4-thiadiazol-2-yl)

Therapeutic Category Carbonic anhydrase inhibitor; use to treat glaucoma, epilepsy, cause a diuretic action (increase the amount of urine excreted); also use to treat temporary paralysis and decreases or prevents symptoms of altitude sickness (during mountain climbing)

Manufacturer / supplier identification

Company: **Emcure Pharmacueticals USA Inc.**

Contact for information: Tel.: 732-238-7880 Fax: +732-238-7881

Emergency telephone No. Tel.: 732-238-7880

Section 2. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component:		
Acetazolamide	Not Available	59-66-5
Inactive Ingredients :		
Microcrystalline Cellulose	Not Available	9004-34-6
Sodium Lauryl Sulfate	Not Available	68585-47-1
Ammonio Methacrylate Copolymer Dispersion Type A/B	Not Found	33434-24-1, 110-44-1, 67-56-1
Sorbic Acid	Not Found	110-44-1
Methanol	Not Found	67-56-1
Talc, Lo Micron	Not Found	14807-96-6

Section 3. Health Hazards Information

Dose and Administration

Glaucoma:
The recommended dosage is 1 capsule (500 mg) two times a day. Usually 1 capsule is administered in the morning and 1 capsule in the evening. It may be necessary to adjust the dose, but it has usually been found that dosage in excess of 2 capsules (1 g) does not produce an increased effect. The dosage should be adjusted with careful individual attention both to symptomatology and intraocular tension. In all cases, continuous supervision by a physician is advisable.

In those unusual instances where adequate control is not obtained by the twice-a-day administration of acetazolamide extended-release capsules, the desired control may be established by means of acetazolamide (tablets or parenteral). Use tablets or parenteral in accordance with the more frequent dosage schedules recommended for these dosage forms, such as 250 mg every four hours, or an initial dose of 500 mg followed by 250 mg or 125 mg every four hours, depending on the case in question.

Acute Mountain Sickness:
Dosage is 500 mg to 1000 mg daily, in divided doses using tablets or extended-release capsules as appropriate. 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 events	**Body as a whole:** Headache, malaise, fatigue, fever, pain at injection site, flushing, growth retardation in children, flaccid paralysis, anaphylaxis. **Digestive:** Gastrointestinal disturbances such as nausea, vomiting, diarrhea. **Hematological/Lymphatic:** Blood dyscrasias such as aplastic anemia, agranulocytosis, leukopenia, thrombocytopenic purpura, melena. **Hepato-biliary disorders:** Abnormal liver function, cholestatic jaundice, hepatic insufficiency, fulminant hepatic necrosis **Metabolic/Nutritional:** Metabolic acidosis, electrolyte imbalance, including hypokalemia, hyponatremia, osteomalacia with long-term phenytoin therapy, loss of appetite, taste alteration, hyper/hypoglycemia **Nervous:** Drowsiness, paresthesia (including numbness and tingling of extremities and face), depression, excitement, ataxia, confusion, convulsions dizziness **Skin:** Allergic skin reactions including urticaria, photosensitivity, Stevens-Johnson syndrome, toxic epidermal necrolysis **Special senses:** Hearing disturbances, tinnitus, transient myopia **Urogenital:** Crystalluria, increased risk of nephrolithiasis with long-term therapy, hematuria, glycosuria, renal failure polyuria
Contraindications	Acetazolamide ER Capsules is contraindicated in patients with: Hypersensitivity to acetazolamide or any excipients in the formulation. Since acetazolamide is a sulfonamide derivative, cross sensitivity between acetazolamide, sulfonamides and other sulfonamide derivatives is possible. 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. It is contraindicated in patients with cirrhosis because of the risk of development of hepatic encephalopathy. Long-term administration of acetazolamide is contraindicated in patients with chronic non-congestive angle-closure glaucoma since it may permit organic closure of the angle to occur while the worsening glaucoma is masked by lowered intraocular pressure
Pregnancy Comments	***Teratogenic effects*** 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 **Nursing Mothers:** Because of the potential for serious adverse reactions in nursing infants from acetazolamide, a decision should be made whether to discontinue nursing or to discontinue the drug taking into account the importance of the drug to the mother. Acetazolamide should only be used by nursing women if the potential benefit justifies the potential risk to the child
Pregnancy Category	*Pregnancy Category C:* .

Section 4. First aid measures

General	Ingestion: If ingestion occurs, induce vomiting immediately and seek medical attention immediately. Never induce committing on an unconscious person.
Overdose Treatment	Overdose in humans is unlikely to occur since Acetazolamide is remarkably non-toxic as shown in animal testing. No specific antidote is known. Treatment should be symptomatic and supportive. Electrolyte imbalance, development of an acidotic state, and central nervous system effects might be expected to occur. Serum electrolyte levels (particularly potassium) and blood pH levels should be monitored. Supportive measures are required to restore electrolyte and pH balance. The acidotic state can usually be corrected by the administration of bicarbonate. Despite its high intraerythrocytic distribution and plasma protein binding properties, acetazolamide may be dialyzable. This may be particularly important in the management of Acetazolamide overdosage when complicated by the presence of renal failure

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. Storage / Spill / Disposal Measures

Storage	Store at 20° to 25°C (68° to 77°F) Dispense in well-closed containers
Spill Response	**Small Spill:** Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements **Large Spill** Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system
Disposal	Dispose the waste in accordance with all applicable Federal, State and local laws.

Section 7. Exposure controls and personal protection

Engineering Controls:
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.

Personal Protection: Safety glasses. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.

Personal Protection in Case of a Large Spill:
Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Exposure Limits: Not available.

Section 8. Physical and chemical properties

Appearance	• Hard Gelatin Capsules, Cap Orange Opaque/Body White Opaque, Cap Imprinted EP in Black Ink and Body Imprinted 107 in Black Ink. Filled with white to off-white pellets.		
Solubility in water	Practically in soluble in water	**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
Percentage Volatile by volume	No Data Available	**Specific gravity**	No Data Available
Vapour pressure	No Data Available		
Other information			

Section 9. Physical Hazards

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

Section 10. 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 specific formulation.

Other — **Carcinogenesis, Mutagenesis, Impairment of Fertility**

Long-term studies in animals to evaluate the carcinogenic potential of acetazolamide has 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 11. Ecological information

No data available on Ecotoxicity

Section 12. Other information

None

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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.