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
(a) Product Identifier: Acetazolamide ER Capsules
(b) Product Code:
   Common/Trade Name: DIAMOX® SEQUELS®, Acetazolamide
   Chemical Name: N-(5-Sulfamoyl-1,3,4-thiadiazol-2-yl)acetamide
   Chemical Family: carbonic anhydrase inhibitor
(c) Distributor: Zydus Pharmaceuticals USA Inc.
   Pennington, NJ 08534
(d) Emergency Telephone: (609) 730-1900

Manufacturer Identification
Company: Heritage Pharma Labs Inc.
Contact for information: Tel.: 732-238-7880 Fax: 732-238-7881

Section 2. Hazard(s) Identification
(a) Classification:
   Skin irritation (Category 2)
   Eye irritation (Category 2A)
   HMIS Rating
   Health Hazard 2
   Flammability 0
   Physical Hazard 0
NFPA Rating

- Health Hazard: 2
- Fire Hazard: 0
- Reactivity Hazard: 0

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):

- Signal Word: Warning

(c) Description of Hazards:

Hazard Statements:
- H315: Causes skin irritation
- H319: Causes serious eye irritation

Precautionary Statements:
- P264: Wash skin thoroughly after handling
- P280: Wear protective gloves/eye protection/face protection
- P302 + P352: IF ON SKIN: Wash with plenty of soap and water
- P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P321: Specific treatment (see supplemental first aid instructions on the label)
- P322 + P313: If skin irritation occurs: Get medical advice/attention
- P337 + P313: If eye irritation persists: Get medical advice/attention
- P362: Take off contaminated clothing and wash before reuse

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.

Overdosage
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.

### Medical Conditions

#### General

Increasing the dose does not increase the diuresis and may increase the incidence of drowsiness and/or paresthesia. Increasing the dose often results in a decrease in diuresis. Under certain circumstances, however, very large doses have been given in conjunction with other diuretics in order to secure diuresis in complete refractory failure.

#### 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 3. Composition / Information on ingredients

<table>
<thead>
<tr>
<th>Components</th>
<th>Exposure Limits</th>
<th>CAS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Active Ingredient</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acetazolamide</td>
<td>Not Found</td>
<td>59-66-5</td>
</tr>
<tr>
<td><strong>Inactive Ingredient</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Microcrystalline Cellulose NF</td>
<td>Not Found</td>
<td>9004-34-6</td>
</tr>
<tr>
<td>Sodium Lauryl Sulfate USP</td>
<td>Not Found</td>
<td>85586-07-8</td>
</tr>
<tr>
<td>Ammonium Methacrylate Copolymer, Type A</td>
<td>Not Found</td>
<td>33434-24-1</td>
</tr>
<tr>
<td>Ammonium Methacrylate Copolymer, Type B</td>
<td>Not Found</td>
<td>33434-24-1</td>
</tr>
<tr>
<td>Talc (Lo Micron)</td>
<td>Not Found</td>
<td>14807-96-6</td>
</tr>
<tr>
<td>Hard gelatin capsules Orange Opaque Cap, White Opaque body (Size 00)</td>
<td>Not Found</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

## Section 4. First-aid measures

### General
Remove from exposure. Remove contaminated Clothing. Person developing serious hypersensitivity reaction must receive medical attention.

### Overdose Treatment
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

<table>
<thead>
<tr>
<th>Fire – fighting measures</th>
<th>Upper Flammable Limit:</th>
<th>Lower Flammable Limit:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flash point</td>
<td>Not Found</td>
<td>Not Found</td>
</tr>
<tr>
<td>Auto-Ignition Temperature:</td>
<td>Not Found</td>
<td>Not Found</td>
</tr>
<tr>
<td>Extinguishing</td>
<td>Water Spray, dry</td>
<td>Fire and Explosion</td>
</tr>
</tbody>
</table>

This material is assumed to be
Safety Data Sheet (SDS)

ACETAZOLAMIDE ER CAPSULES

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

Media: chemical, carbon dioxide or foam as appropriate for surrounding fire and material.

Hazard: 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: Wet acetazolamide with water and absorb with absorbent materials and dispose of according to applicable local, state and federal regulations.

Release to Air: If dust is generated, wear a disposable dust respirator (N95) and reduce exposures by ventilating the area. Clean up spill immediately.

Release to Water: Refer to local water authority. Drain disposal is not recommended; refer to local, state and federal disposal guidelines.

Section 7. Handling and Storage

General Handling: Wear latex or nitrile gloves, safety glasses and a disposable dust mask (N95), wear protective coveralls and shoe covers for larger spills.

Storage Conditions: Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Dispense in well-closed containers.

Section 8. Exposure controls / personal protection

(a) Exposure Limits

<table>
<thead>
<tr>
<th>Compound</th>
<th>Issuer</th>
<th>Type</th>
<th>Exposure Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetazolamide</td>
<td>OSHA</td>
<td>PEL</td>
<td>NE</td>
</tr>
<tr>
<td></td>
<td>ACGIH</td>
<td>TLV</td>
<td>NE</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>NE</td>
</tr>
</tbody>
</table>
Safety Data Sheet (SDS)

ACETAZOLAMIDE ER CAPSULES

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

(b) Engineering Controls

Ventilation  Handle product in a well ventilated area.

(c) Individual Measures

Respiratory Protection  Under normal use, respirators are not required. If dusts are generated, use a disposable dust mask (N95). Personnel wearing respirators should be fit tested and approved for respirator use, under the OSHA Respiratory Protection Standard 29 CFR 1910.134.

Eye Protection  Safety glasses

Skin Protection  Nitrile or Latex Gloves

Other Protective Equipment  Lab Coat

Additional Exposure Precautions  Wash hands following use; no eating, drinking or smoking while handling product.

Section 9. Physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
</table>
| Appearance                     | • Drug Product – Opaque orange cap & white body, hard gelatin capsule, printed (in black) EP on cap and 107 on body.  
                                      • Acetazolamide drug substance – White to faintly yellowish-white crystalline odorless powder. |
| Solubility in water            | Slightly Soluble in water                                                   |
| Boiling point                  | No Data Available                                                           |
| Evaporation rate               | No Data Available                                                           |
| Reactivity in water            | No Data Available                                                           |
| Percentage Volatile by volume  | No Data Available                                                           |
| Vapour pressure                | No Data Available                                                           |
| Odour                          | Odourless                                                                   |
| Melting Point                  | No Data Available                                                           |
| Vapour density                 | No Data Available                                                           |
| Evaporation rate               | No Data Available                                                           |
| Specific gravity               | No Data Available                                                           |
**Section 10. Stability and Reactivity**

(a) Reactivity  
Stable

(b) Chemical Stability  
Stable

(c) Possibility of Hazardous Reactions  
Not known to occur

(d) Conditions to Avoid  
Avoid exposure to extreme heat, light and moisture

(e) Incompatible Materials  
No Data Available

**Section 11. Toxicological Information**

(a) Likely Routes of Exposure  
Primary occupational exposure routes are via inhalation, absorption, or ingestion.

(b) Symptoms related to the physical, chemical and toxicological characteristics  
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.

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.

(c) Delayed and immediate effects and also chronic effects from short and long term exposure  
Gastrointestinal disturbances, vomiting, diarrhea, drowsiness or confusion may result. May cause an allergic reaction or irritation to eyes, nose, or respiratory tract. Fever, rash, ringing in ears, loss of appetite, tingling feeling in extremities may also occur.
(d) **Acute Toxicity**

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>Route</th>
<th>Species</th>
<th>Dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetazolamide</td>
<td>LD&lt;sub&gt;50&lt;/sub&gt;</td>
<td>Intraperitoneal</td>
<td>Rat</td>
<td>2750 mg/kg</td>
</tr>
<tr>
<td>Acetazolamide</td>
<td>LD&lt;sub&gt;50&lt;/sub&gt;</td>
<td>Oral</td>
<td>Mouse</td>
<td>4300 mg/kg</td>
</tr>
<tr>
<td>Acetazolamide</td>
<td>LD&lt;sub&gt;50&lt;/sub&gt;</td>
<td>Intravenous</td>
<td>Mouse</td>
<td>3 mg/kg</td>
</tr>
<tr>
<td>Acetazolamide</td>
<td>LD&lt;sub&gt;50&lt;/sub&gt;</td>
<td>Subcutaneous</td>
<td>Mouse</td>
<td>3 mg/kg</td>
</tr>
<tr>
<td>Acetazolamide</td>
<td>LD&lt;sub&gt;50&lt;/sub&gt;</td>
<td>Intraperitoneal</td>
<td>Mouse</td>
<td>1175 mg/kg</td>
</tr>
<tr>
<td>Acetazolamide</td>
<td>LD&lt;sub&gt;50&lt;/sub&gt;</td>
<td>Intravenous</td>
<td>Dog</td>
<td>&gt;2 mg/kg</td>
</tr>
<tr>
<td>Acetazolamide</td>
<td>LD&lt;sub&gt;50&lt;/sub&gt;</td>
<td>Subcutaneous</td>
<td>Guinea Pig</td>
<td>&gt;1500 mg/kg</td>
</tr>
</tbody>
</table>

(e) **Hazardous Chemical Listings**

- NTP: No
- IARC: No
- OSHA: No

Section 12. **Ecological Information**

(a) **Ecotoxicity**

No applicable ecological information found.

(b) **Persistence and degradability**

No applicable ecological information found.

(c) **Bioaccumulative potential**

No applicable ecological information found.

(d) **Mobility in soil**

No applicable ecological information found.

(e) **Other Adverse Effects**

No applicable ecological information found.

Section 13. **Disposal considerations**

Dispose the waste in accordance with all applicable Federal, State and Local laws.
Safety Data Sheet (SDS)

ACETAZOLAMIDE ER CAPSULES

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

Section 14. Transport Information

(a) UN Number  Not available
(b) UN Proper Shipping Name  Not available
(c) Transport Hazard Class(es)  Not available
(d) Packing Group  Not available
(e) Environmental Hazards  Not available
(f) Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)  Not available
(g) Special Precautions  Not available

DOT: Not Regulated
ICAO/IATA: Not Regulated
IMO: Not Regulated

Section 15. Regulatory Information

Generic Medicine. Approved by USFDA and the ANDA Number is 040904.

Section 16. Other information

None

Date of Issue: 06/02/2015  Supersedes Edition of: New Version of SDS

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.