PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

# PrACETAZOLAMIDE

Acetazolamide Tablets

Tablets, 250 mg, Oral

BP

Carbonic Anhydrase Inhibitor

AA PHARMA INC.
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Date of Initial Authorization:
DEC 31, 1982

Date of Revision:
MAY 7, 2025

Submission Control Number: 292941

## RECENT MAJOR LABEL CHANGES

| | |
|---|---|
| 3 SERIOUS WARNINGS AND PRECAUTIONS BOX | 05/2025 |
| 7 WARNINGS AND PRECAUTIONS | 05/2025 |

## TABLE OF CONTENTS

**Sections or subsections that are not applicable at the time of authorization are not listed.**

## PART I: HEALTH PROFESSIONAL INFORMATION

### 1 INDICATIONS

ACETAZOLAMIDE (acetazolamide tablets) is indicated:

- To decrease ocular aqueous humor secretion in glaucoma (chronic, simple and secondary types).
- For use as an adjunct in the treatment of selected cases of epilepsy.
- To alkalinize the urine in selected cases of salicylate overdosage.

### 1.1 Pediatrics

Pediatrics: No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use.

### 1.2 Geriatrics

Geriatrics: No data are available to Health Canada; therefore, Health Canada has not authorized an indication for geriatric use.

### 2 CONTRAINDICATIONS

ACETAZOLAMIDE is contraindicated for:

- depressed sodium and/or potassium blood levels
- in renal failure.
- adrenal gland failure.
- metabolic acidosis
- some cases of hepatic cirrhosis
- severe glaucoma due to peripheral anterior synechias or in hemorrhagic glaucoma
- long term use in chronic non-congestive angle closure glaucoma

### 3 SERIOUS WARNINGS AND PRECAUTIONS BOX

- The patient should be cautioned to report any unusual skin rash. Severe Cutaneous Adverse Reactions such as Stevens Johnsons Syndrome, Erythema Multiforme, Toxic Epidermal Necrolysis and Acute Generalised Exanthematous Pustulosis may occur with acetazolamide. Hypersensitivity reactions may recur if a sulphonamide or sulphonamide derivative is re-administered, irrespective of the route of administration. If signs of hypersensitivity reactions or other serious reactions occur, acetazolamide must be discontinued.
- The patient may develop shortness of breath or difficulty in breathing after taking acetazolamide. Severe cases of non-cardiogenic pulmonary edema have been reported after taking acetazolamide. Symptoms included dyspnoea, hypoxia and respiratory insufficiency. If non-cardiogenic pulmonary edema is suspected, Acetezolamide should

be withdrawn, and supportive treatment should be given. See 7 WARNINGS AND PRECAUTIONS – Respiratory.

## 4 DOSAGE AND ADMINISTRATION

### 4.2 Recommended Dose and Dosage Adjustment

Chronic simple (open angle) glaucoma: 250 mg. 1 to 4 times daily. A complementary effect has been noted when acetazolamide was used with miotics or mydriatics as the case demanded.

Secondary glaucoma and preoperative treatment of some cases of acute congestive (closed angle) glaucoma: 250 mg every 4 hours.

Epilepsy: 8 to 30 mg/kg (375 to 1000 mg) daily in divided doses.

To alkalinize the urine: 250 mg every 4 to 6 hours.

Health Canada has not authorized an indication for pediatric use.

## 5 OVERDOSAGE

For the most recent information in the management of a suspected drug overdose, contact your regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669).

## 6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

**Table – Dosage Forms, Strengths, Composition and Packaging**

| Route of Administration | Dosage Form / Strength/Composition | Non-medicinal Ingredients |
|---|---|---|
| Oral | Tablet 250 mg | Colloidal silicon dioxide, Magnesium stearate, Microcrystalline cellulose. |

ACETAZOLAMIDE (acetazolamide) 250 mg tablets: Each white, round, biconvex tablet, cross-scored on one side and engraved 250 on the other side contains acetazolamide 250 mg. Available in bottles of 100.

## 7 WARNINGS AND PRECAUTIONS

Please see 3 SERIOUS WARNINGS AND PRECAUTIONS BOX.

### General

Increasing the dose does not increase, and may often decrease the diuresis, and may yet produce drowsiness and/ or paresthesia.

**Opthalmologic**

Acetazolamide, a sulfonamide, can cause an idiosyncratic reaction resulting in choroidal effusion associated with acute myopia, acute angle-closure glaucoma or a combination of both. Symptoms include acute onset of decreased visual acuity, blurred vision or ocular pain. These typically occur within hours to weeks of drug initiation. Discontinue acetazolamide as rapidly as possible. Obtain appropriate medical evaluation immediately and consider treatment of elevated intraocular pressure.

**Respiratory**

Severe cases of non-cardiogenic pulmonary edema have been reported after taking acetazolamide, also after a single dose see 8.1 Adverse Reaction Overview. Non-cardiogenic pulmonary edema typically developed within minutes to hours after acetazolamide intake. Symptoms included dyspnoea, hypoxia, and respiratory insufficiency. If non-cardiogenic pulmonary edema is suspected, acetazolamide should be withdrawn, and supportive treatment should be given. Acetazolamide should not be administered to patients who previously experienced non-cardiogenic pulmonary edema following acetazolamide intake.

## 7.1 Special Populations

### 7.1.2 Breast-feeding

It is unknown if acetazolamide is excreted in human milk. Precaution should be exercised because many drugs can be excreted in human milk.

### 7.1.3 Pediatrics

**Pediatrics:** No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use.

# 8 ADVERSE REACTIONS

## 8.1 Adverse Reaction Overview

Metabolic acidosis and hypokalemia may occur during prolonged acetazolamide therapy.

Adverse reactions common to all sulfonamide derivatives including fever, rash (including Stevens Johnsons Syndrome, Erythema Multiforme, Toxic Epidermal Necrolysis and Acute Generalised Exanthematous Pustulosis), crystalluria, renal calculus, bone marrow depression, thrombocytopenic purpura, hemolytic anemia, leukopenia, pancytopenia, and agranulocytosis may occur. If such reactions occur, discontinue therapy and institute appropriate measures.

For acute respiratory distress syndrome and pulmonary edema, if rapidly progressive dyspnoea, hypoxaemia, or chest X-ray abnormalities such as diffuse infiltrative shadow in both lungs are observed, administration of this drug should be discontinued, and appropriate measures should be taken. The frequency of these adverse reactions are not known.

Untoward effects during short term therapy are said to be minimal. Those noted include paresthesias, some loss of appetite, polyuria and occasional instances of drowsiness and confusion. Other occasional adverse reactions include urticaria, melena, hematuria, glycosuria, hepatic insufficiency, flaccid paralysis and convulsions.

Transient myopia has been reported. This condition invariably subsided upon the diminution or discontinuation of the medication.

### 8.5 Post-Market Adverse Reactions

Eye disorders: choroidal effusion, acute myopia, acute angle-closure glaucoma (very rare).

## 9 DRUG INTERACTIONS

### 9.2 Drug Interactions Overview

Drug interactions have not been established.

### 9.4 Drug-Drug Interactions

Interactions with other drugs have not been established.

### 9.5 Drug-Food Interactions

Interactions with food have not been established.

### 9.6 Drug-Herb Interactions

Interactions with herbal products have not been established.

### 9.7 Drug-Laboratory Test Interactions

Interactions with laboratory tests have not been established.

## 10 CLINICAL PHARMACOLOGY

This information is not available for this drug product.

## 11 STORAGE, STABILITY AND DISPOSAL

Store at room temperature 15 - 30°C.

Keep out of reach and sight of children.

## 12 SPECIAL HANDLING INSTRUCTIONS

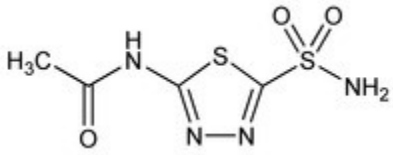
There are no special handling instructions.

## PART II: SCIENTIFIC INFORMATION

## 13 PHARMACEUTICAL INFORMATION

| | |
|---|---|
| Proper name: | Acetazolamide |
| Chemical name: | N-[5-(Aminosulfonyl)-1,3,4-thiadiazol-2-yl] acetamide |
| Molecular formula: | $C_4H_6N_4O_3S_2$ |
| Molecular mass: | 222.24 g/mol |
| Physicochemical properties: | Crystals from water, mp 258-259 °C (effervescence). Weak acid. pKa 7.2. Sparingly sol in practically boiling water. Slightly sol in alcohol, acetone. Very slightly sol in water. Practically insol in carbon tetrachloride, chloroform, ether. Soly (mg/ml): polyethylene glycol-400 87.81; propylene glycol 7.44; ethanol 3.93; glycerin 3.65; water 0.72. |

Structural formula:




**Product Characteristics:**

Each ACETAZOLAMIDE 250 mg tablet contains 250 mg acetazolamide with the following non-medicinal ingredients: colloidal silicon dioxide, magnesium stearate, microcrystalline cellulose.

## 14 CLINICAL TRIALS

This information is not available for this drug product.

## 15 MICROBIOLOGY

No microbiological information is required for this drug product.

## 16 NON-CLINICAL TOXICOLOGY

Studies on acetazolamide in mice and rats have consistently demonstrated embryocidal and teratogenic effects at doses in excess of 10 times the human dose. There is no evidence of these effects in humans; however, acetazolamide should not be used in pregnancy, unless the anticipated benefits outweigh these potential hazards and are not attainable in other ways. See 2 CONTRAIDICATIONS.

**PATIENT MEDICATION INFORMATION**

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

**PrACETAZOLAMIDE**

**Acetazolamide Tablets**

Read this carefully before you start taking **ACETAZOLAMIDE** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ACETAZOLAMIDE**.

**Serious Warnings and Precautions**

**Serious Skin Reactions:** ACETAZOLAMIDE can cause serious skin reactions including Stevens Johnsons Syndrome, Erythema Multiforme, Toxic Epidermal Necrolysis and Acute Generalised Exanthematous Pustulosis. Stop taking ACETAZOLAMIDE and get immediate medical help if you have any of the following symptoms while you are taking ACETAZOLAMIDE:

- skin peeling, scaling, or blistering (with or without pus) which may also affect your eyes, mouth, nose or genitals
- itching, severe rash, bumps under the skin, skin pain, skin color changes (redness, yellowing, purplish)
- swelling and redness of eyes or face
- flu-like feeling, fever, chills, body aches, swollen glands, cough
- lung or breathing problems, shortness of breath or difficulty breathing

**Lung Problems**: ACETAZOLAMIDE can cause a severe case called non-cardiogenic pulmonary edema. Stop taking ACETAZOLAMIDE and get immediate medical help if you have any of the following symptoms while you are taking ACETAZOLAMIDE:

- shortness of breath
- difficultly breathing
- headache
- coughing or wheezing
- abnormal heart rate

**What is ACETAZOLAMIDE used for?**

ACETAZOLAMIDE is used in adults to:

- treat glaucoma (a condition of the eye), by reducing the pressure within the eye.
- treat epilepsy (fits or convulsions).
- reduce the amount of acid in the urine (alkalinize) in patients who have overdosed on a salicylate medicine (used to treat pain, fever and inflammation).

**How does ACETAZOLAMIDE work?**

ACETAZOLAMIDE belongs to a group of medicines known as carbonic anhydrase inhibitors.

**What are the ingredients in ACETAZOLAMIDE?**

Medicinal ingredients: Acetazolamide

Non-medicinal ingredients: Colloidal silicon dioxide, Magnesium stearate, Microcrystalline cellulose.

**ACETAZOLAMIDE comes in the following dosage forms:**

Tablets: 250 mg.

**Do not use ACETAZOLAMIDE if:**

- you have low blood levels of sodium and potassium
- you have kidney problems, including kidney failure
- you have problems with your adrenal glands – glands above the kidneys
- you have a problem with your electrolytes causing an imbalance in your body's acid base balance (metabolic acidosis)
- you have severe liver problems
- you have severe glaucoma or hemorrhagic glaucoma
- you have a particular type of glaucoma known as chronic non congestive angle closure glaucoma
- you are pregnant

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ACETAZOLAMIDE. Talk about any health conditions or problems you may have, including if you:**

- are breastfeeding. It is not known if ACETAZOLAMIDE passes into breastmilk.
- have experienced lung or breathing problems (such as fluid in the lungs) after taking acetazolamide in the past.

**Other warnings you should know about:**

**Blood tests and monitoring:** ACETAZOLAMIDE can cause abnormal blood and urine test results. Your healthcare professional will decide when to preform the necessary tests and will interpret the results.

**Eye problems**: ACETAZOLAMIDE can cause sudden eye disorders such as:

- Choroidal effusion: an abnormal buildup of liquid in your eye that may result in vision changes.
- Myopia: sudden nearsightedness or blurred vision.
- Glaucoma: an increased pressure in your eyes, eye pain. May lead to permanent vision loss if untreated.

If your vision changes, stop taking ACETAZOLAMIDE and seek medical help. These eye disorders are related and can develop within hours to weeks of starting ACETAZOLAMIDE.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**How to take ACETAZOLAMIDE:**

Always take ACETAZOLAMIDE exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.

**Usual dose:**

Glaucoma: 250 mg, 1 to 4 times daily.

Epilepsy: 375 mg to 1000 mg daily in divided doses. Your healthcare professional will decide on the dose that is right for you based on your body weight.

To alkalinize the urine: 250 mg every 4 to 6 hours.

**Overdose:**

If you think you, or a person you are caring for, have taken too much ACETAZOLAMIDE, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

**Missed Dose:**

If you forget to take a dose of ACETAZOLAMIDE, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose. Do not take two doses at the same time to make up for a missed dose.

**What are possible side effects from using ACETAZOLAMIDE?**

These are not all the possible side effects you may have when taking ACETAZOLAMIDE. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- fever
- loss of appetite
- drowsiness

- confusion
- numbness or tingling of the skin
- muscle weakness

| Serious side effects and what to do about them | | | |
|---|---|---|---|
| **Symptom / effect** | **Talk to your healthcare professional** | | **Stop taking drug and get immediate medical help** |
| | **Only if severe** | **In all cases** | |
| **COMMON** | | | |
| **Bone marrow suppression:** infections (fever, chills, sore throat, mouth ulcers), weakness, fatigue, easy bruising, bleeding of the nose, gums or mouth, tiny red spots on the skin, rash, shortness of breath, pale skin, lips and nail beds | | | ✓ |
| **Kidney problems (including kidney stones):** cloudy urine, blood in urine, urinating more than usual, sharp pain on the side and back, pain or burning when urinating, nausea, vomiting | | ✓ | |
| **Serious skin reactions (Stevens Johnsons Syndrome, Erythema Multiforme, Toxic Epidermal Necrolysis and Acute Generalised Exanthematous Pustulosis):** skin peeling, scaling, or blistering (with or without pus) which may also affect your eyes, mouth, nose or genitals, itching, severe rash, bumps under the skin, skin pain, skin color changes (redness, yellowing, purplish), swelling and redness of eyes or face, flu-like feeling, fever, chills, | | | ✓ |

| Serious side effects and what to do about them | | | |
|---|---|---|---|
| **Symptom / effect** | **Talk to your healthcare professional** | | **Stop taking drug and get immediate medical help** |
| | **Only if severe** | **In all cases** | |
| body aches, swollen glands, cough | | | |
| **UNKNOWN** | | | |
| **Abnormal bleeding:** black tarry stool, blood in urine | | ✓ | |
| **Eye problems:**<br>**- Choroidal effusion** (buildup of liquid in your eyes): blind spots, eye pain, blurred vision<br>**- Myopia:** sudden near sightedness or blurred vision<br>**- Glaucoma:** increased pressure in your eye, eye pain | | | ✓ |
| **Liver problems (including liver failure):** yellowing of the whites of the eyes or skin, itchiness, dark urine, pale stool, weight gain, abdominal swelling and pain, loss of appetite, shortness of breath, disorientation or confusion | | ✓ | |
| **Lung problems** (pulmonary edema (fluid in the lungs), acute respiratory distress syndrome, hypoxaemia (low oxygen in the blood)): headache, coughing, wheezing, shortness of breath, difficulty breathing, abnormal heart rate | | | ✓ |
| **Seizures:** fits, uncontrollable shaking of the body with or without loss of consciousness | | | ✓ |

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

**Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

**Storage:**

Store at room temperature 15 - 30°C.

Keep out of reach and sight of children.

**If you want more information about ACETAZOLAMIDE:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website (https://www.aapharma.ca/en/), or by calling 1-877-998-9097.

This leaflet was prepared by AA PHARMA INC., 1165 Creditstone Road Unit #1, Vaughan, Ontario, L4K 4N7.

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