PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

PrACETAZOLAMIDE

Acetazolamide Tablets

Tablets, 250 mg, Oral

Carbonic Anhydrase Inhibitor

BP

AA PHARMA INC.
1165 Creditstone Road, Unit #1
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JUN 03, 2010

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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).
- Also used 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

Depressed sodium and/or potassium blood levels, in renal failure, adrenal gland failure, metabolic acidosis, and 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 is contra-indicated.

3 SERIOUS WARNINGS AND PRECAUTIONS BOX

Serious Warnings and Precautions

- 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.

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 management of a suspected drug overdose, contact your regional poison control centre.

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.

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

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.

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.

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

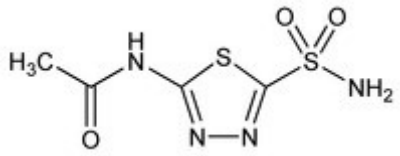
There are no special handling instructions.

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

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).
- ~~To~~ 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.

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.

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, or regional poison control centre immediately, even if there are no 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			
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			✓

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	
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			
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			✓
UNKNOWN			
Seizures: fits, uncontrollable shaking of the body with or without loss of consciousness			✓
Abnormal bleeding: black tarry stool, blood in urine		✓	
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		✓	

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 (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health 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 1-8 77-998-9097.

This leaflet was prepared by AA PHARMA INC.

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