PRESCRIBING INFORMATION

ACETAZOLAMIDE

Acetazolamide Tablets BP

250 mg

Carbonic Anhydrase Inhibitor

AA PHARMA INC.
1165 Creditstone Road, Unit #1
Vaughan, Ontario
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Control Number:214651

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June 03, 2010

DATE OF REVISION:
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THERAPEUTIC CLASSIFICATION

Carbonic Anhydrase Inhibitor

INDICATIONS

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.

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.

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.

PRECAUTIONS

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

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.

ADVERSE EFFECTS

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.

DOSAGE

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.

AVAILABILITY OF DOSAGE FORMS

Each white, scored, compressed tablet contains: acetazolamide BP 250 mg. Identified 250. Bottles of 100 and 500.

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