120.00 mm

170.00 mm

Tablet

Acemit 250 mg

(Acetazolamide)

ٹیبلیٹ

ایسیمیٹ ۲۵۰ ملی گرام

(ایسیٹازولامائیڈ)

COMPOSITION
Each tablet contains:
Acetazolamide ……250mg
(USP Specifications)

DESCRIPTION
Acetazolamide is an enzyme inhibitor which acts specifically on carbonic anhydrase effective in the control of fluid secretion, in the treatment of certain convulsive disorders and in the promotion of diuresis in instances of abnormal fluid retention.

INDICATIONS
Glaucoma: Acetazolamide Tablets are useful in glaucoma (chronic simple (open angle) glaucoma, secondary glaucoma, and perioperatively in acute angle closure glaucoma where delay of surgery is desired in order to lower intraocular pressure) because it acts on inflow, decreasing the amount of aqueous secretion.
Abnormal retention of fluids: Acetazolamide is a diuretic whose effect is due to the effect on the reversible hydration of carbon dioxide and dehydration of carbonic acid reaction in the kidney. The result is renal loss of HC03- ion which carries out sodium, water and potassium. Acetazolamide Tablets can be used in conjunction with other diuretics when effects on several segments of the nephron are desirable in the treatment of fluid retaining states
Epilepsy: In conjunction with other anticonvulsants best results with Acetazolamide Tablets have been seen in petit mal in children. Good results, however, have been seen in patients, both children and adults, with other types of seizures such as grand mal, mixed seizure patterns, myoclonic jerk patterns etc.

MECHANISM OF ACTION
Acetazolamide is an inhibitor of carbonic anhydrase. By inhibiting the reaction catalysed by this enzyme in the renal tubules, acetazolamide increases the excretion of bicarbonate and of cations, chiefly sodium and potassium, and so promotes alkaline diuresis.
Continuous administration of acetazolamide is associated with metabolic acidosis and resultant loss of diuretic activity. Therefore, the effectiveness of Acetazolamide Tablets in diuresis diminishes with continuous use. By inhibiting carbonic anhydrase in the eye, acetazolamide decreases intra-ocular pressure and is therefore useful in the treatment of glaucoma.

DOSAGE & ADMINISTRATION
Glaucoma (simple acute congestive and secondary):
Adults: 250 - 1,000 mg (1 - 4 tablets) per 24 hours, usually in divided doses for amounts over 250 mg daily.
Abnormal retention of fluid:
Congestive heart failure, drug-induced oedema.
Adults: For diuresis, the starting dose is usually 250 - 375 mg (1-1½ tablets) once daily in the morning. If, after an initial response, the patient fails to continue to lose oedema fluid, do not increase the dose but allow for kidney recovery by omitting a day. Best results are often obtained on a regime of 250 -375 mg (1-1½ tablets) daily for two days, rest a day, and repeat, or merely giving the Acetazolamide tablets every other day. The use of Acetazolamide tablets does not eliminate the need for other therapy, e.g. digitalis, bed rest and salt restriction in congestive heart failure and proper supplementation with elements such as potassium in drug-induced oedema.For cases of fluid retention associated with pre-menstrual tension, a daily dose (single) of 125- 375 mg is suggested.
Epilepsy:
Adults: 250 - 1,000 mg daily in divided doses.
Children: 8-30 mg/kg in daily divided doses and not to exceed 750 mg/day.
The change from other medication to Acetazolamide Tablets should be gradual.
Elderly: Acetazolamide Tablets should only be used with particular caution in elderly patients or those with potential obstruction in the urinary tract or with disorders rendering their electrolyte balance precarious or with liver dysfunction.

PHARMACOKINETICS
Absorption
Acetazolamide is fairly rapidly absorbed from the gastro-intestinal tract with peak plasma concentrations occurring about 2 hours after administration by mouth.
Distribution
It has been estimated to have a plasma half-life of about 4 hours. It is tightly bound tocarbonic anhydrase and accumulates in tissues containing this enzyme, particularlyred blood cells and the renal cortex. It is also bound to plasma proteins.
Elimination
It is excreted unchanged in the urine; renal clearance being enhanced in alkalineurine.

WARNINGS & PRECAUTIONS
Suicidal ideation and behavior have been reported in patients treated with antiepileptic agents in several indications. A meta-analysis of randomised placebo-controlled trials of anti-epileptic drugs has also shown a small increased risk of suicidal ideation and behavior. The mechanism of this risk is unknown, and the available data do not exclude the possibility of an increased risk for Acetazolamide.
Therefore, patients should be monitored for signs of suicidal ideation and behaviours and appropriate treatment should be considered. Patients (and caregivers of patients) should be advised to seek medical advice should signs of suicidal ideation or behaviour emerge. Increasing the dose does not increase the diuresis and may increase the incidence of drowsiness and/or paraesthesia.
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.
When Acetazolamide Tablets are prescribed for long-term therapy, special precautions are advisable. The patient should be cautioned to report any unusual skin rash. Periodic blood cell counts, and electrolyte levels are recommended.
Fatalities have occurred, although rarely, due to severe reactions to sulphonamides. A precipitous drop in formed blood cell elements or the appearance of toxic skin manifestations should call for immediate cessation of Acetazolamide Tablets therapy.
In patients with pulmonary obstruction or emphysema where alveolar ventilation may be impaired, Acetazolamide tablets may aggravate acidosis and should be used with caution.
In patients with a past history of renal calculi, benefit should be balanced against the risks of precipitating further calculi.
The occurrence at the treatment initiation of a feverish generalized erythema associated with pustula may be a symptom of acute generalized exanthematous pustulosis (AGEP). In case of AGEP diagnosis, acetazolamide should be discontinued, and any subsequent administration of acetazolamide contraindicated.
Cases of choroidal effusion/detachment have been reported after the use of acetazolamide. Symptoms include acute onset of decreased visual acuity or ocular pain and can occur within hours after initiation of acetazolamide treatment.
If choroidal effusion/detachment is suspected, acetazolamide should be discontinued asrapidly as possible.
Pregnancy
Acetazolamide has been reported to be teratogenic and embryotoxic in rats, mice, hamsters and rabbits at oral or parenteral doses in excess of ten times those recommended in human beings. Although there is no evidence of these effects in human beings, there are no adequate and well-controlled studies in pregnant women. Therefore, Acetazolamide tablets should not be used in pregnancy, especially during the first trimester.
Breast-feeding
Acetazolamide has been detected in low levels in the milk of lactating women who have taken Acetazolamide tablets. Although it is unlikely that this will lead to any harmful effects in the infant, extreme caution should be exercised when Acetazolamide tablets is administered to lactating women.

SIDE EFFECTS
Blood and lymphatic system disorders
Thrombocytopenia, Leukopenia, Aplastic anemia, Bone marrow depression, Pancytopenia, Agranulocytosis.
Metabolism and nutrition disorder
Metabolic acidosis, electrolyte imbalance and thirst.
Psychiatric disorders
Depression, Irritability, reduced libido, Occasional instances of confusion.
Nervous system disorders
Paraesthesia, particularly a "tingling" feeling in the extremities, dizziness, Headache, Occasional instances of drowsiness, convulsions, Flaccid paralysis.
Eye disorders
Transient myopia, Choroidal effusion, Choroidal detachment.
Ear and labyrinth disorders
Impaired hearing and tinnitus.
Gastrointestinal disorders
Melaena, Taste disturbance, Nausea, Vomiting, Diarrhea.
Hepatobiliary disorders
Fulminant hepatic necrosis, Hepatitis or cholestatic jaundice.
Skin and subcutaneous tissue disorders
Urticaria, Rash (including Erythema multiforme, Stevens-Johnson syndrome, Toxic epidermal necrolysis) Thrombocytic purpura, Photosensitivity, acute generalized exanthematous pustulosis (AGEP).
Renal and urinary disorders
Haematuria, Crystalluria, Renal and ureteral colic, Renal lesions, Renal failure, Calculus formation, Glycosuria, Polyuria.
General disorders and administration site conditions
Fever, Fatigue, Anaphylaxis, Flushing.

DRUG INTERACTIONS
Acetazolamide is a sulfonamide derivative. Sulfonamides may potentiate the effects of folic acid antagonists. Possible potentiation of the effects of folic acid antagonists, hypoglycaemics and oral anti-coagulants may occur. Concurrent administration of acetazolamide and aspirin may result in severe acidosis and increase central nervous system toxicity. Adjustment of dose may be required when Acetazolamide Tablets are given with cardiac glycosides or hypertensive agents.
When given concomitantly, acetazolamide modifies the metabolism of phenytoin, leading to increased serum levels of phenytoin. Severe osteomalacia has been noted in a few patients taking acetazolamide in combination with other anticonvulsants. There have been isolated reports of reduced primidone and increased carbamazepine serum levels with concurrent administration of acetazolamide.
Because of possible additive effects, concomitant use with other carbonic anhydrase inhibitors is not advisable.
By increasing the pH of renal tubular urine, acetazolamide reduces the urinary excretion of amphetamine and quinidine and so may enhance the magnitude and the duration of effect of amphetamines and enhance the effect of quinidine.
Ciclosporin: Acetazolamide may elevate ciclosporin levels.
Methenamine: Acetazolamide may prevent the urinary antiseptic effect of methenamine.
Lithium: Acetazolamide increases lithium excretion and the blood lithium levels may be decreased.
Sodium bicarbonate: Acetazolamide and sodium bicarbonate used concurrently increases the risk of renal calculus formation.

CONTRAINDICATIONS
Acetazolamide is contra-indicated in situations in which sodium and/or potassium blood levels are depressed, in cases of marked kidney and liver disease or dysfunction, suprarenal gland failure, and hyperchloremic acidosis. Acetazolamide Tablets should not be used in patients with hepatic cirrhosis as this may increase the risk of hepatic encephalopathy. Long-term administration of Acetazolamide Tablets is contra-indicated 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. Acetazolamide Tablets should not be used in patients hypersensitive to sulphonamides.

OVER DOSAGE
No specific antidote. Supportive measures with correction of electrolyte andfluid balance. Force fluids.

STORAGE & INSTRUCTIONS
Store below 30°C.
Protect from heat, sunlight and moisture.
Keep away from the reach of children.
To be sold on the prescription of a registered medical practitioner only.

HOW SUPPLIED
30 Tablets

خوراک وطریقہ استعمال:
ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایات:
دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت میں رکھیں۔
دھوپ، کرمی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔
صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

Manufactured by:
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Lahore, Pakistan.