Bharat Parenterals Limited
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CIN NO: U24231GJ1992PLC018237

Zolamox-250 -SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. Name of the medicinal product

1.1. Name of the medicinal product:

Generic Name/INN Name: Acetazolamide Tablets BP 250 mg

Trade Name: Zolamox-250

1.2 Strength:

Acetazolamide BP .....250 mg

1.3 Pharmaceutical form:

Solid oral dosage form- Tablet

2. Qualitative and Quantitative composition:

Sr. No.	Ingredients	Spec.	Label Claim	Qty./Tablet (mg)	%w/w	Function
Mixing						
1.	Acetazolamide	BP	250.00	250.00	46.30	Active
2.	Maize starch	BP	---	100.00	18.52	Diluent
3.	Calcium Hydrogen Phosphate Dihydrate	BP	---	125.00	23.15	Diluent
Binding						
4.	PVP K 30	BP	---	24.00	4.44	Binder
5.	Purified water***	BP	---	120.00	---	Solvent
Lubrication						
6.	Magnesium stearate	BP	---	5.300	0.98	Lubricant
7.	Crospovidone	BP	---	25.700	4.76	Disintegrant
Total weight of uncoated tablet				**530.00**		
Film Coating						
8.	Isopropyl Alcohol***	BP	---	66.500	---	Solvent
9.	Titanium Dioxide	BP	---	1.000	0.19	Opacifier
10.	Purified Talc	BP	---	1.500	0.28	Antitacking agent
11.	Methylene Chloride***	BP	---	123.50	---	Coating solvent
12.	HPMC E-5	BP	---	7.500	1.39	Film forming agent
Total weight of coated tablet				**540.00**	**100.00**	

*** Evaporate during manufacturing process.

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3. Pharmaceutical form:

Dosage Form: Oral Dosage form (Tablets)

Visual & Physical characteristics of the product: A white coloured circular, biconvex, film coated tablet having embossed "conical flask B" on one side and '+' on other side of the tablets.

4. Clinical particulars:

4.1. Therapeutic indications:

Acetazolamide is an enzyme inhibitor which acts specifically on carbonic anhydrase. Acetazolamide is indicated in adults and children.

It is indicated in the treatment of:

- Glaucoma: Acetazolamide is 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 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 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.

4.2. Posology and method of administration:

- Glaucoma (simple, acute congestive and secondary): Adults: 250 - 1,000mg (1-4 tablets) per 24 hours, usually in divided doses for amounts over 250mg daily.
- Abnormal retention of fluid: Congestive heart failure, drug-induced oedema.

  Adults: For diuresis, the starting dose is usually 250 - 375mg (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

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results are often obtained on a regime of 250 - 375mg (1-1½ tablets) daily for two days, rest a day, and repeat, or merely giving the Acetazolamide 250mg tablets every other day.

The use of Acetazolamide 250mg 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 - 375mg is suggested.

- Epilepsy:
  Adults: 250 - 1,000mg daily in divided doses.
  Children: 8-30mg/kg in daily divided doses and not to exceed 750mg/day. The change from other medication to acetazolamide should be gradual.
  Elderly: Acetazolamide 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.

Method of administration: For oral administration.

4.3. 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 250mg tablets should not be used in patients with hepatic cirrhosis as this may increase the risk of hepatic encephalopathy. Long-term administration of acetazolamide 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 250mg tablets should not be used in patients hypersensitive to the active substance, sulphonamides or to any of the excipients related to this formulation.

4.4 Special warnings and precautions for use:

Suicidal ideation and behaviour 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 behaviour. The

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mechanism of this risk is not known 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 is 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 therapy.

In patients with pulmonary obstruction or emphysema where alveolar ventilation may be impaired, acetazolamide 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 generalised exanthematous pustulosis (AGEP) (See section 4.8). In case of AGEP diagnosis, acetazolamide should be discontinued, and any subsequent administration of acetazolamide contraindicated.

4.5 Interaction with other medicinal products and other forms of interaction:

Acetazolamide is a sulphonamide derivative. Sulphonamides 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 this medicine is 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.

4.6 Pregnancy and lactation:

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 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.

Fertility: there is no human or animal data available on the effect of acetazolamide on fertility

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