Ecox Tablet 400mg

Name and Strength of Active Ingredient (s)

No.	Substance	Quantity Unit Per Dose
1	ETHAMBUTOL HYDROCHLORIDE	400.00;mg;;0

Dosage Form: Tablet
Tablet, coated film

Product Description
White, circular, shallow, biconvex, film coated tablets with break line on one side and plain on other side.

Pharmacodynamics
Mechanism of action
Ethambutol at the recommended doses is a bacteriostatic that acts specifically against tubercle bacilli, also those resistant to other antimycobacterial agents. It possesses very little sterilizing activity. One suggested mechanism of action is that ethambutol inhibits cell wall synthesis by preventing the incorporation of mycolic acids.
Ethambutol is active against virtually all strains of *Mycobacterium tuberculosis* and *M. bovis* and is also active against other mycobacteria such as *M. Kansasii.* When ethambutol has been used alone for treatment of tuberculosis, tubercle bacilli from these patients have developed resistance to ethambutol hydrochloride by in vitro susceptibility tests; the development of resistance has been unpredictable and appears to occur in a step-like manner. No cross resistance between ethambutol and other antituberculous agents has been reported. Ethambutol has reduced the incidence of the emergence of mycobacterial resistance to isoniazid when both drugs have been used concurrently.

Pharmacokinetics
Approximately 80% of Ethambutol is absorbed after oral administration. Following intake of 15 mg/kg body weight, a peak serum concentration of approximately 4 mg/l is achieved in 2-4 hrs.
When the drug is administered daily for longer periods of time at this dose, serum levels are similar.
The intracellular concentrations of erythrocytes reach peak values approximately twice those of plasma and maintain this ratio throughout the 24 hours. The mean volume of distribution has been estimated to 3.89 l/kg - 8.1 l/kg.
It is reported that, depending on the administered dose, about 10-40% of the drug is bound to plasma protein. The plasma concentration falls biphasically, the half-life being about 4 hrs initially and 10 hrs subsequently; 50 to 70% of the dose being excreted unchanged in the urine and another 7 to 15% as inactive aldehyde and carboxylic acid metabolites. The main metabolic pathway appears to be an initial oxidation of the alcohol to an aldehydic intermediate, followed by conversion to a dicarboxylic acid. Twenty to 22% of the initial dose is excreted in the faeces as unchanged drug. The elimination of the drug is delayed in subjects with reduced renal function.

Indication
Ethambutol Tablets is used in combination with other antituberculosis agents for the treatment of all forms of tuberculosis caused by *Mycobacterium tuberculosis.*
Ethambutol Tablets 400mg is also used in the treatment of infections caused by atypical mycobacteria, such as *Mycobacterium avium complex (MAC).*

Recommended Dose
Initial treatment (patients never on antituberculosis therapy):
15 mg/kg body weight as a single oral dose once every 24 hours.
In the more recent studies, isoniazid has been administered concurrently in a single, daily, oral dose.
Retreatment (patients previously on antituberculosis therapy):
25 mg/kg body weight as a single oral dose once every 24 hours.
Concurrently administer at least one other antituberculous drug to which the organisms have been demonstrated to be susceptible.
It is not recommended for use in patients below 13 years old.

Mode Of Administration
Oral

Contraindication
Hypersensitivity to the active substance or to any of the excipients.
Ethambutol is generally contraindicated in patients with optic neuritis.

Warning and Precautions
Patients should be advised to report promptly any changes in visual acuity since ethambutol causes ocular toxicity. Control of visual acuity should be performed prior to therapy and every four weeks during treatment; in patients with pre-existing visual defects or renal impairment every second week and when considered necessary more frequently.
Patients who cannot report their visual acuity should be closely monitored for signs of ocular toxicity when treated with ethambutol.
Ophthalmologic examination should include tests for black-white/chromatic visual acuity (e.g. Snellen eye chart and 65-test) and ophthalmoscopy.
Therapy with ethambutol must be discontinued immediately if visual disturbances emerge.
Since ethambutol is mainly eliminated via the kidneys, dose adjustment is required in patients with impaired renal function. Visual acuity should be monitored more closely in these patients.
Ethambutol is excreted via the same pathway as uric acid, thereby leading to increased serum concentration of uric acid. Concomitant therapy with isoniazid or pyridoxine may enhance this effect. Patients with pre-existing hyperuricaemia or symptoms of gout should be monitored for signs of deterioration when treated with ethambutol.

Interactions With Other Medicaments
Aluminium hydroxide impairs the absorption of ethambutol. During therapy with ethambutol acidsuppressing drugs or antacids not containing aluminium hydroxide should be used.
Doses of uricosurics may need to be increased, since ethambutol competes with uric acid for its renal excretion (see section Warning and precautions and Side effects).
Concomitant therapy with disulfiram may increase the risk for ocular toxicity.
Disulfiram is a drug used to support the treatment of chronic alcoholism by producing an acute sensitivity to alcohol. Disulfiram, a chelating agent, may produce a toxic optic neuropathy.

Both Ethambutol and Disulfiram are having the neurotoxic side effects, and the concomitant administration of the Ethambutol with other neurotoxic medications (Disulfiram) may increase the risk of developing the neurotoxicity.

Pregnancy and Lactation

As ethambutol is excreted through breast milk, its use should only be considered if the expected benefit to the mother outweighs the potential risk to the infant.

Side Effects

The most important adverse effect of ethambutol is retrobulbar neuritis with a reduction in visual acuity.

The adverse events considered at least possibly related to the treatment are listed below by body system, organ class and absolute frequency. They are not based on adequately sized randomized controlled trials, but on published literature data generated mostly during post-approval use.

Therefore, often no frequency data can be given. Frequencies are defined as very common (≥1/10), common (≥1/100, <1/10), uncommon (≥1/1000, <1/100), rare (≥1/10,000, <1/1000), very rare (≤1/10,000), 'not known'.

Nervous system disorders

Common: visual disturbances due to optic neuritis (retrobulbar neuritis). The frequency depends on the dose and duration of therapy. Optic neuritis has been reported in up to 3% of patients receiving ethambutol 20 mg/kg/day. Typical initial signs include impairment of colour vision (red-green blindness) and constriction of visual field (central or peripheral scotoma). These changes are often reversible upon discontinuation of therapy. To avoid development of irreversible optic atrophy visual acuity should be regularly monitored and ethambutol therapy must be immediately discontinued when visual disturbances occur.

Not known: Peripheral neuropathy (paraesthesia), especially in the legs, dizziness, headache, tremor.

Psychiatric disorders

Not known: confusion, disorientation, hallucination.

Gastrointestinal disorders

Not known: metallic taste, nausea, vomiting, anorexia, flatulence, abdominal pain.

Hepatobiliary disorders

Not known: jaundice, transient increases in liver enzymes.

Renal and urinary disorders

Very common: increases in uric acid, especially in patients with gout.

Not known: nephrotoxicity including interstitial nephritis.

General disorders

Not known: allergic reactions with skin reactions (exanthema, erythema), pruritus, fever, leucopenia, anaphylaxia, allergic pneumonitis, neutropenia, eosinophilia, Stevens-Johnson syndrome.

Blood and lymphatic systems disorders

Not known: thrombocytopenia, leucopenia (allergic), neutropenia with eosinophilia.

Respiratory, thoracic and mediastinal disorders

Not known: pneumonitis (allergic).

Musculoskeletal disorders:

Not known: gout.

Symptoms And Treatment of Overdose
Symptoms: Anorexia, vomiting, gastrointestinal disturbances, fever, headache, dizziness, hallucinations and/or visual disturbances.
Treatment: Emesis and gastric lavage may be of value if undertaken within a few hours of ingestion. Subsequently, haemo- or peritoneal dialysis may be of value. There is no specific antidote and treatment is supportive.

Storage Condition
Do not store above 30°C.

Keep out of reach and sight of children.

Shelf Life
36 months

Nature and contents of container
Carton pack (100 tablets) of 10 blister strips each of 10 tablets: Primary packaging is a blister of aluminium foil and amber colour PVC/PVDC foil.
Carton pack (672 tablets) of 24 blister strips each of 28 tablets: Primary packaging is a blister of aluminium foil and amber colour PVC/PVDC foil.

Manufactured in India by:
Macleods Pharmaceuticals Ltd.
Plot No: 25-27, Survey No. 366,
Premier Industrial Estate, Kachigam,
Daman 396210, India.
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