Products: E 400-B and E 400

ETHAMBUTOL

General information

A synthetic congener of 1,2-ethanediamine that is active against M. tuberculosis, M. bovis and some non-specific mycobacteria. It is used in combination with other anti-TB drugs to prevent or delay the emergence of resistant strains.

It is readily absorbed from the gastrointestinal tract. Plasma concentrations peak in 2-four hours and decay with a half-life of three to four hours. Ethambutol is excreted in the urine both unchanged and as inactive hepatic metabolites.

About 20% is excreted in the faeces as unchanged drug.

Clinical information

Uses

An optional component of several anti-TB chemotherapeutic regimens currently recommended by WHO.

Dosage and administration

By mouth:
Adults: 15 mg/kg daily
30 mg/kg three times weekly, or
45 mg/kg (40-50 mg/kg) twice a week

Children: 15 mg/kg daily

Dosage must always be carefully calculated on a weight basis to avoid toxicity, and should be reduced in patients with impaired renal function.

Contraindications

• Known hypersensitivity
• Pre-existing optic neuritis from any cause
• Inability to report symptomatic visual disturbances—children under 5 years)
• Severe renal impairment

Precautions

- Visual disturbances—ocular examination recommended before and during treatment (see note below)
- Reduce dose in renal impairment and monitor plasma concentration
- Use in the elderly
- Use during pregnancy

Note: Patients should report visual disturbances immediately and discontinue treatment; children who are incapable of reporting symptomatic visual changes accurately should be given

alternative therapy, as should, if possible, any patient who cannot understand warnings about visual adverse effects

Whenever possible, renal function should be assessed before treatment.

Use in pregnancy

The six month regimen based upon isoniazid, rifampicin and pyrazinamide should be used. If a fourth drug is needed during the initial phase, ethambutol should be preferred to streptomycin.

Adverse effects

Dose-dependent optic neuritis can readily result in impairment of visual acuity and colour vision. Early changes are usually reversible, but blindness can occur if treatment is not discontinued promptly.

Signs of peripheral neuritis occasionally develop in the legs.

Overdosage

Emesis and gastric lavage may be of value if undertaken within a few hours of ingestion. Subsequently, dialysis may be of value. There is no specific antidote and treatment is supportive.

Storage

Tablets should be stored in well-closed containers.