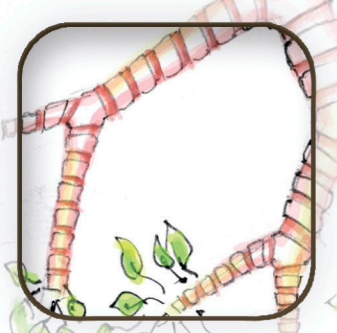
YURIA·PHARM

INBUTOL

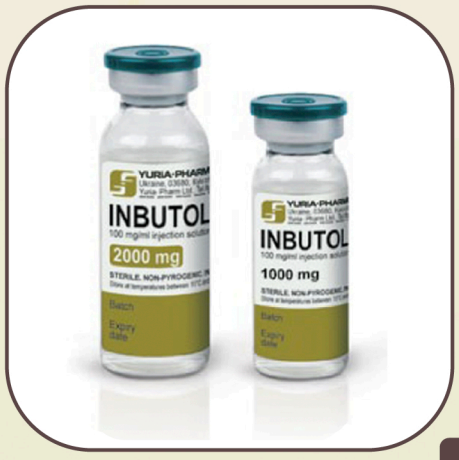


– Intravenous form of Ethambutol

– 100 % controlled treatment

– 100 % bioavailability

– Maximal efficiency + Maximal safety



Control and Effectiveness!

INBUTOL
(ethambutol)

Composition: 1 ml of the solution contains 100 mg ethambutol hydrochloride;
Pharmaceutical form. Injection solution.
Pharmacological properties

PHARMACODYNAMICS

Inbutol has a specific antibacterial tuberculostatic effect on Mycobacterium tuberculosis and Mycobacterium bovis, as well as some atypical (opportunistic, non-tuberculosis) kinds of mycobacteria, Mycobacterium avis. The drug is not active against other bacteria, viruses or fungi. Has a bacteriostatic action. Inhibits the growth and development of tuberculosis mycobacteria
resistant to other anti-tuberculosis drugs. Primary resistance of Mycobacterium tuberculosis and Mycobacterium bovis to ethambutol is uncommon, while secondary resistance develops slowly (except for cases of monotherapy with the drug), which is why the drug should be used combined with other antituberculosis agents. Inbutol penetrates actively growing mycobacterial cells, inhibits the synthesis of RNA and one or several metabolites, disrupts cellular metabolism, stops cell fission and leads to cell death. It is only active against actively fissioning cells.

PHARMACOKINETICS

The drug takes effect immediately after intravenous administration of 10 ml of 10% solution (1000 mg). Maximum blood concentration is achieved immediately after administration and maintained for 2-4 hours. Blood protein binding is 20-30%. The drug easily penetrates tissues and organs, as well as bodily fluids, except for ascitic and pleural fluids. The highest concentrations are observed in the kidneys, lungs, saliva and urine. Enters breast milk. Does not penetrate the undamaged hematoencephalic barrier. Partially metabolized in the liver (15%),
creating inactive metabolites. Half-life is approximately 6 hours, or 8 hours in patients with renal disorders. Eliminated with the urine - 80 to 90% (50% unchanged, 15% as inactive metanolites) – and feces – 10-20% (unchanged). Eliminated during hemodialysis and peritoneal dialysis.

INDICATIONS FOR USE

Treatment of all forms and localizations of active tuberculosis in adults and children, especially with newly diagnosed acute processes.

ADMINISTRATION AND DOSES

The optimal adult daily dose of intravenous ethambutol (Inbutol®) is a single dose of 12-20 mg per kg of body mass (10-12 ml) for daily administration, or daily doses of 20-27 mg/kg of body pass (12-16 ml) administered every other day. In patients with widespread smear-positive processes, and for treatment of tubercular meningoencephalitis, the dose can be increased to 20-30 mg/kg of body pass per day (12-16 ml). The maximum daily adult dose is 1.0 – 1.6 g (10-16 ml) depending on the body mass. The drug can be prescribed in children aged 5 and older, in single daily doses of 15-20 mg/kg of body mass (10-12 ml) or intermittent doses of up to 25 mg/kg of body mass (12 ml). The maximum daily dose for children is 1.0 – 1.2 g (10-12 ml) depending on the body mass. The total treatment course dose depends on the severity of the condition and is determined by the physician. The treatment duration depends on the therapy effectiveness and drug receptiveness, 2-4 months on average. In patients with renal function disorders and creatinine level over 1.3%, the elimination rate must be monitored. For elimination rates over 50 ml/min, the Inbutol dose of 20 mg/kg (12 ml) does not require adjustment. For elimination rates under 50 ml/min, the dose should be decreased to 12 mg/kg (10 ml).

For elimination rates under 20 ml/min, Inbutol serum concentration must be determined, and the dose adjusted so that it is approximately 5 μg/ml. As an alternative treatment for patients with renal insufficiency or patients undergoing dialysis, Inbutol is prescribed in doses of 40 mg/kg of body mass, twice weekly. In patients undergoing dialysis, the drug should be administered 6 hours before the start of dialysis.
The drug is administered by intravenous drop infusion, after dissolving the necessary dose in 100-200 ml of 0.9% of sodium chloride solution or 5% glucose solution. The recommended time of infusion for 200 ml of solution is 90-120 min.

Side effects

Possible development of retrobulbar neurosis, limited field of vision, lowered acuity of sight and perception of the color green, retinal hemorrhage, vertigo, headache, paresthesia, dyspeptic conditions, increased coughing, expectoration difficulties, increased phlegm viscosity. Long-term administration of large doses may cause myocardium damage and development of heart failure, gout aggravation, leucopenia, allergic reactions.

Contraindications

Individual hypersensitivity to the drug, history of optic nerve damage, gout, cataract, diabetic retinopathy, lactation, terminal stage of renal failure, age under 5.

Overdosing

Manifested as vertigo, nausea, vomiting, diarrhea, peripheral neurosis, sight impairment. In such cases the drug therapy should be ceased. Intravenous drop infusion of Ringer solution, sorbilactum, rheosorbilactum, artificial diuresis. B group vitamins prescribed.

Special administration information

Caution must be exercised when prescribed in patients with
renal function impairment. Ethambutol penetrates the placenta and enters the fetus tissues, where its concentration can reach 74.5% of the mother's serum concentration. Ethambutol enters breast milk, where it reaches approximately the same concentration as in the blood plasma. No connection has been established during ethambutol administration during pregnancy and fetus development anomalies. Prescription to pregnant and lactating women is possible if the risk for the fetus does not exceed the benefit for the mother. Ethambutol is not recommended for children under 5, due to lack of reliable results of sight condition tests. ЛEthambutol treatment may
increase blood urate concentration due to impaired renal elimination of uric acid. In case of side effects, the dose should be adjusted downwards, and if that is not possible, switched to intermittent administration (every other day or twice weekly). The symptoms can be alleviated by prescribing of B group vitamins and expectorants. The drug is prescribed in combination with other antituberculosis drugs, as well as pluripotential antiobiotics, fluoroquinolones, sulfanilamides and other drugs. Caution must be exercised in patients with elevated blood uric acid concentrations.

Interaction with other drugs

Pharmacological antagonism with ethionamide, spermine, sperdimine and magnesium. Ethambutol reacts with blood phentolamine and may increase arterial pressure. Increases the nephrotoxicity of aminoglycosides, asparaginase, ciprofloxacin and metothrexate.

Shelf life and storage conditions

Keep out of reach of children. Store in a dry, dark place, at temperatures between 15 and 25°C.
Shelf life – 2 years.
Sales list. Prescription only.
Упаковка. По 10 и 20 мл раствора во флаконах.

ЮРІЯ·ФАРМ

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