DESCRIPTION
Ethionamide is used in the treatment of tuberculosis. It is a second-line anti-tubercular agent. It may also be used for treatment of leprosy. The chemical name for ethionamide is 2-ethylpyridine-4-carbothioamide. It is a yellow coloured, round, biconvex enteric coated tablet.

COMPOSITION
Each enteric coated tablet contains:

Ethionamide IP ...................250 mg.

PHARMACOLOGY
Antibacterial Activity: Ethionamide is a bacteriostatic drug which acts by inhibiting protein synthesis in the cell and inhibits mycolic acid synthesis. The multiplication of Mycobacterium tuberculosis is suppressed by concentrations of ethionamide ranging from 0.6 to 2.5 mg/ml. Resistance can develop rapidly in vitro and in vivo. A concentration of 10 mg/ml or less will inhibit approximately 75% of photochromogenic mycobacteria; the scotochromogens are more resistant. M. tuberculosis strains which have become resistant to drugs such as isoniazid, streptomycin and PAS remain ethionamide-sensitive.

PHARMACOKINETICS
The oral administration of 1 g of ethionamide yields peak concentrations in plasma of about 20 mg/ml in 3 hours. The half-life of the drug is about 2 hours. Approximately 50% of patients are unable to tolerate a single dose larger than 500 mg because of gastrointestinal disturbances. Ethionamide is rapidly and widely distributed; the concentrations in the blood and various organs are approximately equal. Significant concentrations are present in CSF. Ethionamide, like aminosalicylic acid, inhibits the acetylation of isoniazid in vitro. Less than 1% of ethionamide is excreted in active form in the urine.

INDICATIONS
Recommended for any form of tuberculosis when treatment with first line drug has failed. Use with other effective antitubercular drugs.

CONTRAINDICATIONS
Severe hypersensitivity to ethionamide.
Severe hepatic damage.

WARNING
Use in pregnancy
Teratogenic effects have been demonstrated in small animals receiving doses in excess of those recommended for human beings. Use of the drug should be avoided during pregnancy or in women of childbearing potential unless the benefits outweigh its possible hazard.

**Use in children**
Optimum dosage for children has not been established. This, however, does not preclude use of the drug when its use is crucial to therapy.

**PRECAUTIONS**
Pretreatment examinations should include *in vitro* susceptibility tests of recent cultures of *M. tuberculosis* from the patient as measured against Ethionamide and the usual primary antituberculous drugs. Determinations of serum transaminase (SGOT, SGPT) should be made prior to and every 2 to 4 weeks during therapy. In patients with diabetes mellitus, management may be more difficult and hepatitis occurs more frequently.

**DRUG INTERACTIONS**
Ethionamide may intensify the adverse effects of other antitubercular drugs administered concomitantly. Convulsions have been reported and special care should be taken particularly when ethionamide is administered with cycloserine.

**ADVERSE REACTIONS**
The most common reactions to ethionamide are anorexia, nausea, and vomiting. A metallic taste also may be noted. Severe postural hypotension, mental depression, drowsiness, and asthenia are common. Convulsions and peripheral neuropathy are rare. Other reactions referable to the nervous system include olfactory disturbances, blurred vision, diplopia, dizziness, paresthesias, headache, restlessness and tremors. Severe allergic skin rashes, purpura, stomatitis, gynecomastia, impotence, menorrhagia, acne, and alopecia also have been observed. Hepatitis has been associated with the use of the drug in about 5% of cases. The signs and symptoms of hepatotoxicity clear when treatment is stopped. Hepatic function should be assessed at regular intervals in patients receiving ethionamide.

**ADMINISTRATION AND DOSAGE**
Administer with at least 1 other effective antituberculous drug.

**Average adult dose:** 0.5 to 1 g/day in divided doses with food.

**Children:** A dose of 15 to 20 mg/kg/day (maximum 1 g) has been recommended.
Concomitant administration of pyridoxine is recommended.

**STORAGE**
Store in a cool, dry and dark place.

**REFERENCES**