ISONIAZID tablets

Anti T.B.

Composition:

Each tablet contains:

- Isonicotinic acid hydrazide 50 & 100 mg (Isoniazid I.N.H).

Indications & Usage:

ISONIAZID Tablets is recommended for all forms of tuberculosis in which organisms are susceptible. However, active tuberculosis must be treated with multiple concomitant anti-tuberculosis medications to prevent emergence of drug resistance. Single-drug treatment of active tuberculosis with Isoniazid, or any other medication, is inadequate therapy.

Isoniazid is recommended as preventive therapy for T.B.

Clinical Pharmacology:

Isoniazid acts against actively growing tubercle bacilli. Within one to two hours after oral administration. Isoniazid produces peak blood levels which decline to 50 percent or less within six hours. It diffuses readily into all body fluids (cerebrospinal, pleura and ascetic), tissues, organs and excretion (saliva, sputum and feces). The drug also passes through the placental barrier and into milk in concentrations comparable to those in the plasma. From 50 to 70 percent of a dose of isoniazid is excreted in the urine in 24 hours.

Mechanism of Action:

Isoniazid inhibits the synthesis of mycolic acids, an essential component of the bacterial cell wall. At therapeutic levels isoniazid is bactericidal against actively growing intracellular and extracellular Mycobacterium tuberculosis or Isoniazid-resistant Mycobacterium tuberculosis bacilli develop rapidly when isoniazid monotherapy is administered.

Contraindications:

Isoniazid is contraindicated in patients who develop severe hypersensitivity
reactions, including drug-induced hepatitis, previous isoniazid-associated hepatic injury: severe adverse reactions to Isoniazid such as drug fever, chills, arthritis: and acute liver disease of any etiology.

Warning:

- Severe and sometimes fatal hepatitis associated with isoniazid therapy has been reported and may occur or may develop even after many months of treatment.

- The risk of developing hepatitis is age related.

- The risk of hepatitis is increased with daily consumption of alcohol.

Over-dosage:

Signs and Symptoms

Isoniazid over dosage produces signs and symptoms within 30 minutes to three hours after ingestion. Nausea, vomiting, dizziness, slurring of speech, blurring of vision and visual hallucinations (including bright colors and strange designs) are among the early manifestations. With marked over dosage, respiratory distress and CNS depression, severe metabolic acidosis, acetonuria and hyperglycemia are typical laboratory findings.

Dosage & Administration:

For Treatment of Tuberculosis

Drug susceptibility testing should be performed on the organism initial isolated from all patient with newly diagnosed tuberculosis if the bacilli becomes resistant therapy must be changed to agents to which the bacilli are susceptible.

For Adults:

The total daily dose used commonly is 3-5 mg/kg of body weight (with a maximum of 300 mg daily) taken orally as single or divided doses after meals. The dose may be duplicated in severely ill patients.

For Children:

10-20 mg/kg of body weight. (With a maximum of 300 mg daily) after meals.
The dose is adjusted by the physician when it is used with other anti-tubercular drugs Vitamin B6 (Pyridoxine) in a dose of 15-50 mg/day is given during treatment to counteract the neurotoxicity.

Storage:

Store at controlled room temperature 15-30 °C Protect from light.

Packing:

- ISONIAZID 50 mg Tablets: Box of 100 Tablets in 10 strips each of 10 tablets.
- ISONIAZID 100 mg Tablets: Box of 50 Tablets in 5 strips each of 10 tablets.