Natrapharm

Rx

ISONIAZID + PYRIDOXINE HCl

CURAZID® FORTE

200mg/10mg per 5mL syrup
Antituberculosis

FORMULATION:
Each 5mL of Curazid Forte syrup contains:
Isoniazid.....200mg
Pyridoxine hydrochloride (Vitamin B_6).....10mg

INDICATIONS:
Isoniazid is indicated for the primary treatment of pulmonary tuberculosis and extrapulmonary tuberculosis.

PHARMACODYNAMICS
Isoniazid is highly active against Mycobacterium tuberculosis which it inhibits in vitro at concentrations of 0.02 to 0.2ug per mL. Isoniazid may have activity against some strains of the mycobacteria including *M. kansasii*.
Although it is rapidly bactericidal against actively dividing *M. tuberculosis*, it is considered to be only bacteriostatic against semi-dormant organisms and has less sterilizing activity than rifampicin or pyrazinamide.

PHARMACOKINETICS
Peak concentrations of about 3 to 8 ug per mL appear in blood 1 to 2 hours after a fasting dose of 300mg by mouth. The rate and extent of absorption of isoniazid is reduced by food. Isoniazid is not considered to be bound appreciably to plasma proteins and diffuses into all body tissues and fluids, including the CSF. It appears in fetal blood it given during pregnancy and is distributed to breast milk.

The plasma half-life for isoniazid ranges from about 1 to 6 hours, those who are fast acetylators having shorter half-lives. The primary metabolic route is the acetylation of isoniazid to acetylisoniazid by N-acetytransferase found in the liver and small intestine. Acetylisoniazid is then hydrolyzed to isonicotinic acid and monoacetyhydrazine; isonicotlnic acid is conjugated with glycine to isonicotinyl glycine (isonicotinuric acid) and monoacetyhydrazine is further acetylated to diacetylhydrazine. Some unmetabolised isoniazid is conjugated to hydrazones. The metabolites of isoniazid have no tuberculostatic activity and, apart from possibly monoacetyhydrazine, they are also less toxic. In patients with normal renal function, over 75% of a dose appears in the urine in 24 hours, mainly as metabolites. Small amounts of drug are also excreted in the feces. Isoniazid is removed by dialysis.

WARNINGS AND PRECAUTIONS
Isoniazid should be administered with caution to patients with convulsive disorders, a history of psychosis or hepatic or renal dysfunction. Patients who are at risk of neuropathy or pyridoxine deficiency, including those who are diabetic, alcoholic, malnourished, uraemic, pregnant, or infected with HIV, should receive pyridoxine usually in a dose of 10mg daily, although some have suggested using up to 50mg daily. If symptoms of hepatitis such as malaise, fatigue, anorexia, and nausea develop isoniazid should be discontinued pending evaluation.

Liver function should be checked before treatment with isoniazid and special care should be taken in alcoholic patients or those with pre-existing liver disease.

Hypersensitivity: Stop all drugs and evaluate the first sign of a hypersensitivity reaction. Careful monitoring of hepatic function is recommended.

INTERACTIONS
Inhibits the metabolism of the following drugs: anticonvulsants (i.e Carbamazepine, phenytoin, primidone and valproic acid), benzodiazepines, haloperidol, ketoconazole, theophylline and warfarin.

Concomitant antacid administration may reduce the absorption of Isoniazid.
Corticosteroids may decrease the serum concentration of Isoniazid by increasing acetylation rate and/or renal clearance.

ADVERSE EFFECTS:
Isoniazid is generally well tolerated at currently recommended doses. However, patients who are slow acetylators of Isoniazid appear to have a higher incidence of some adverse effects.

CNS: Patients whose nutrition is poor are at risk of peripheral neuritis. Other neurological adverse events include psychotic reactions and convulsions Pyridoxine may be given to prevent or treat these adverse effects. Optic neuritis has also been reported.

Haematological effects: include various aneamias, agranulocytosis, thrombocytopenia and eosinophilia.

Pregnancy & Lactation
Isoniazid exerts an embryocidal effect in both rats and rabbits, but no Isoniazid related congenital anomalies have been found in reproduction studies in mammalian species. Prescribe during pregnancy only when therapeutically necessary. Use With caution if benefits outweigh risks. Isoniazid appears in breast milk, observe breastfed infants for any evidence of adverse effects.

TREATMENT OF ADVERSE EFFECTS
Pyridoxine hydrochloride 10mg daily has been recommended to prophylaxis of peripheral neuritis associated with isoniazid although some have suggested using up to 50mg daily.

CAUTION
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

DOSAGE AND ADMINISTRATION
Usual adult dose is 300mg daily by mouth on an empty stomach.
Children: 5mg per kg body weight daily with a maximum of 300mg daily.
For intermittent therapy, 10mg per kg body weight three times a week or 15mg per kg body weight twice a week. (maximum of 900mg)
Doses may need to be reduced in patients with hepatic impairment or moderate to severe renal impairment.
In tuberculosis prophylaxis, daily dose of 300mg are given for at least 6 months and sometimes for up to 1 year. Or as prescribed by the physician.

AVAILABILITY
Amber Glass Bottle x 120 mL (Box of 1 's)

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph

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STORE AT TEMPERATURES NOT EXCEEDING 30°C

Manufactured for
Natrapharm, Inc.
The Patriot Building
Km. 18, West Service Road,
SLEX, Sucat, Parañaque City
by Lloyd Laboratories, Inc.
No. 10 Lloyd Avenue,
First Bulacan Industrial City,
City of Malolos, Bulacan

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