# ESPERAL

(Disulfiram Tablets U.S.P., 250 mg)

**DESCRIPTION :**
Esperal (Disulfiram) produces a sensitivity to alcohol which results in a highly unpleasant reaction when the patient under treatment ingests even small amounts of alcohol. It is indicated as an adjuvant in the treatment of carefully selected and co-operative chronic alcoholics.

**CLINICAL PHARMACOLOGY :**
Esperal markedly alters the intermediary metabolism of alcohol. It blocks the oxidation of alcohol at the acetaldehyde stage. When ethanol is given to an individual previously treated with Esperal the blood acetaldehyde concentration rises five to ten times higher than in an untreated individual. This effect is accompanied by marked signs and symptoms, known as the acetaldehyde syndrome, manifested by flushing, throbbing in head and neck, respiratory difficulty, nausea, vomiting, sweating, thirst, chest pain, palpitation, syncope, vertigo and blurred vision.

Esperal is absorbed from the gastrointestinal tract and is rapidly reduced to diethyldithio carbamate principally by the glutathione reductase system in the erythrocytes. Reduction may also occur in the liver. Diethyldithiocarbamate is metabolised in the liver to its glucoronide and methylester and to diethylamine, carbon disulfide and sulphate ions. Metabolites are excreted primarily in the urine, carbon disulphide is exhaled in the breath.

**INDICATIONS :**
Esperal is indicated as an adjuvant in the treatment of carefully selected and co-operative chronic alcoholics.

**CONTRAINDICATIONS :**
Esperal is contraindicated in cardiac failure, coronary artery disease, previous history of CVA, hypertension, severe personality disorder, suicidal risk or psychosis.

Esperal is also contraindicated in patients receiving or have recently received metronidazole, paraldehyde, alcohol or alcohol containing preparation.

**PRECAUTIONS :**
In case of renal or hepatic insufficiency caution should be exercised. Caution should also be observed in case of respiratory disease, diabetes mellitus and epilepsy.

Patients with a history of rubber contact dermatitis, should be evaluated for hyper sensitivity to thiuram derivatives before receiving Esperal. Patients taking Esperal should not be exposed to ethylene dibromide or its vapors.

**WARNINGS :**
It is advisable that before starting the treatment with Esperal, the appropriate examination should be carried out to establish the suitability of the patient for treatment. The patient must be fully informed of the Esperal-alcohol reaction. He must be strongly cautioned against surreptitious drinking while taking the drug and he must be fully aware of possible consequences.

Patients should be warned to avoid alcohol in disguised form i.e. in vinegars, cough syrups, etc. He should also be informed that reactions may occur even upto 14 days after ingesting drug.

**USE IN PREGNANCY, LACTATION AND CHILDREN :**
The use of Esperal in first trimester of pregnancy is not advised. Because of scanty reports, the use of Esperal is not advised in lactating females especially where there is a possibility of interaction with medicines that the baby may be taking.

Esperal is not recommended in children.

**ADVERSE EFFECTS :**
Esperal is a very safe, non toxic drug. During initial treatment with Esperal, drowsiness and fatigue may occur. Nausea, vomiting, halitosis and reduction in libido have been observed with Esperal. If side effects are marked, dosage should be reduced. There are occasional reports of allergic dermatitis, peripheral neuritis and hepatic cell damage.

**DRUG INTERACTIONS :**
Esperal may potentiate the toxic effects of warfarin, antipyrine, phenytoin, chlordiazepoxide and diazepam by inhibiting their metabo¬lism. A few reports of increase in confusion and changes in affect behaviour have been noted with the concurrent administration of metronidazole, isoniazid or paraldehyde. Potentiation of organic brain syndrome with amitriptyline and choreoathetosis following pimozide have occured very rarely. The intensity of the Esperal alcohol reaction may be increased by chlorpromazine and amitriptyline and decreased by diazepam. Esperal inhibits the oxidation and renal excretion of rifampicin.

**DOSAGE AND ADMINISTRATION :**
Esperal should never be administered until the patient has abstained from alcohol for atleast 12 hours.

Initial Dosage Schedule: In the first phase of treatment, a maximum of 500 mg daily is given in a single dose for One to two weeks. Although usually taken in the morning, Esperal may be taken on retiring by patients who experience a sedative effect. Alternatively, to minimize, or eliminate, the sedative effect, dosage may be adjusted downward.

The average maintenance dose is 250 mg daily (range 125 to 500 mg), it should not exceed 500 mg daily. In the routine management of the alcoholics, it is not recommended to carry out an alcohol challenge test. If the clinician feels an alcohol challenge is essential for the success of therapy full information on the procedure and risk of this test can be obtained from the company. Administration of Esperal must be continued until the patient is fully recovered socially and a basis for permanent self control is established. Depending on the individual patients, maintenance therapy may be required for months, or even years. In case of renal and hepatic insufficiency, caution should be exercised and dosage should be reduced proportionately.

**OVERDOSAGE :**
Esperal itself is a very safe drug. There has been reports of the ingestion of quantities 25 gm causing central and peripheral neurological symptoms, which have resolved without sequelae.

**PRESENTATION** :
Esperal is available in blister strip of 10 tablets, each containing Disulfiram Tablets U.S.P., 250 mg.

torrent PHARMA

Manufactured by :
TORRENT PHARMACEUTICALS LTD.
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