

Tryptin[®]

Amitriptyline Hydrochloride USP

COMPOSITION

Tryptin[®] 10 tablet: Each film coated tablet contains Amitriptyline Hydrochloride USP 10 mg.

Tryptin[®] 25 tablet: Each film coated tablet contains Amitriptyline Hydrochloride USP 25 mg.

PHARMACOLOGY

Tryptin[®] (Amitriptyline) is a tricyclic antidepressant. It has marked anticholinergic and sedative properties. It prevents the reuptake of noradrenaline and serotonin at nerve ending. Amitriptyline hydrochloride is rapidly absorbed from the GI tract. Peak plasma concentrations occur within 2-12 hours. Amitriptyline is excreted in the urine, mainly in the form of its metabolites.

INDICATION

Tryptin[®] is indicated for depressive illness, particularly with anxiety and nocturnal enuresis in children.

DOSAGE AND ADMINISTRATION

Depression:

Adults: Initially 75mg a day in divided doses or 50-100 mg as a single dose at night at bed time. Dose can be increased by 25 or 50 mg at bed time as necessary to a total of 150 mg per day.

For elderly patients and adolescents: 30 mg daily in three divided doses with 20 mg at bed time.

Usual maintenance dose is 50-100 mg daily.

Nocturnal enuresis:

6-10 years: 10-20 mg at bed time.

11-16 years: 25-50 mg at bed time for 3 months and gradually withdrawn.

CONTRAINDICATION AND PRECAUTION

Amitriptyline is contraindicated in myocardial infarction, arrhythmias, particularly heart block of any degree, mania and severe liver disease. Initially sedation may affect the ability to drive or operate machinery. It should be used with caution in patients with a history of epilepsy, glaucoma, urinary retention, cardiac disease, diabetes, pregnancy, hepatic impairment, thyroid disease, increased intra-ocular pressure and psychoses (may aggravate mania).

ADVERSE EFFECT

Dry mouth, sedation, blurred vision, constipation, nausea, difficulty with micturition. Other common side effects are arrhythmia, tachycardia, sweating, tremor, rashes, behavioral disturbances (particularly with children), confusion (particularly in the elderly), and interference with sexual function, blood sugar changes and weight changes. Less commonly black tongue, paralytic ileus, convulsions, agranulocytosis, leukopenia, eosinophilia, purpura, thrombocytopenia and jaundice.

USAGE IN PREGNANCY

Pregnancy Category- C

Amitriptyline has been shown to cross the placenta. Amitriptyline should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the fetus.

USAGE IN NURSING MOTHERS

Amitriptyline is excreted into breast milk. Because of the potential for serious adverse reactions in nursing infants from Amitriptyline, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

STORAGE CONDITION

Store in a cool and dry place, below 30° C. Protect from light and moisture.

HOW SUPPLIED

Tryptin[®] 10 tablet: Each box containing 200 film coated tablets in strip pack.

Tryptin[®] 25 tablet: Each box containing 200 film coated tablets in strip pack.

Manufactured by
 **SQUARE**
PHARMACEUTICALS LTD.
BANGLADESH