

Amilin®

Amitriptyline Hydrochloride

Description

Amitriptyline Hydrochloride (Amilin®) is a potent antidepressant in patients with endogenous depression.

Mode of action

Amitriptyline hydrochloride (Amilin®) has three major pharmacological actions.

- a. It inhibits the reuptake of serotonin and noradrenaline and thus reduces depression and increases mood.
- b. It binds with histamine receptors and produces sedation which is required for patients having depression with anxiety.
- c. It tights the lower sphincter of urinary bladder and prevents nocturnal enuresis.

Pharmacokinetics

Amitriptyline hydrochloride (Amilin®) is completely but slowly absorbed from the gastrointestinal tract after oral administration and peak plasma concentrations are usually reached within 4-8 hours. The elimination occurs over a period of several days. Plasma half-life ranges from 10 to 28 hours. Amitriptyline undergoes extensive hepatic presystemic elimination and its systemic bioavailability has been reported to range between 33-62%. Because of its high lipophilicity, amitriptyline is widely distributed throughout the body and extensively bound to tissue and plasma proteins. It is highly bound (about 95%) to plasma proteins.

Composition

Amilin® 10 mg Tablet: Each tablet contains Amitriptyline Hydrochloride BP 10 mg.

Amilin® 25 mg Tablet: Each tablet contains Amitriptyline Hydrochloride BP 25 mg.

Indications

Endogenous depression with anxiety, nocturnal enuresis of children, prophylaxis of migraine, tension headache, chronic pain.

Dosage & administration

Depression: Initially 75 mg (elderly and adolescents 30-75 mg) daily in divided doses, or as a single dose at bedtime, increased gradually upto 150-200 mg if necessary. Child under 16 years is not recommended for depression. Nocturnal enuresis: Child 7-10 years, 10-20 mg; 11-16 years, 25-50 mg at night; maximum period of treatment (including gradual withdrawal) is 3 months; full physical examination is required before further course.

Contraindications

Prostatic hypertrophy, glaucoma, recovery phase after myocardial infarction.

Side effects

Side effects include dry mouth, sedation, blurred vision, and changes in accommodation, constipation and urinary retention. Tolerance to these effects tends to develop with continued use of the drug. Fatigue, dizziness, weakness,

tremor and headache are attributable to the central effects. Extrapyramidal symptoms have been documented with amitriptyline hydrochloride. Confusional reactions and delirium may occur in the elderly.

Use in pregnancy & lactation

The safety of amitriptyline hydrochloride in pregnancy has not been completely established. It may be advisable to avoid the use of amitriptyline hydrochloride during pregnancy, at least in the early stages, unless there exists a compelling need for it. It is probably best to avoid during breast-feeding.

Precautions

Cardiac disease, history of epilepsy, mania and psychosis. Abrupt withdrawal should be avoided.

Drug interactions

Amitriptyline hydrochloride potentiates the activity of alcohol and antagonizes the activity of methyldopa. Concurrent administration of amitriptyline hydrochloride and MAO inhibitors may result convulsion and coma. Activity of amitriptyline hydrochloride may be reduced by barbiturates.

Over dosage

Ingestion of 750 mg or more by an adult may result in severe toxicity. The effects in overdose will be potentiated by simultaneous ingestion of alcohol and other psychotropic drugs.

Overdose effects are mainly due to anticholinergic (atropine-like) effects at autonomic nerve endings and in the brain. There is also a quinidine-like effect on the myocardium.

Storage

Keep out of reach of children. Store in a dry place, below 25°C temperature and protected from light.

Packaging

Amilin® 10 mg Tablet: Each carton contains 14X10 tablets in alu-alu blister pack.

Amilin® 25 mg Tablet: Each carton contains 14X10 tablets in alu-alu blister pack.

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