Tablets

AMOTRIP- 25mg

(Amitriptyline HCl B.P)

Antidepressant

Indications And Clinical Uses: Amitriptyline may be used in depressive illness of psychotic or endogenous nature and in selected patients with neurotic depression. Endogenous depression is more likely to be alleviated than are other depressive states. Amitriptyline, because of its sedative action, is also of value in alleviating the anxiety component of depression.

Contra-Indications: In patients who have shown prior hypersensitivity to it, it should not be given concomitantly with a MAO inhibiting compound. Hyperpyretic crises, severe convulsions, and deaths have occurred in patients receiving tricyclic antidepressant and MAO inhibitor, a minimum of 14 days should be allowed to elapse after the latter is discontinued. Amitriptyline should then be initiated cautiously with gradual increase in dosage until optimum response is achieved.

Warnings In Clinical States: Amitriptyline should be used with caution in patients with a history of seizures, impaired liver function, a history of hepatic damage or blood dyscrasias and, because of its atropine-like action, in patients with a history of urinary retention, or with narrow-angle glaucoma or increased intraocular pressure. In patients with narrow-angle glaucoma, doses may precipitate an attack. There has been a report of fatal dysrhythmia occurring as late as 56 hours after amitriptyline overdose. Patients with cardiovascular disorders should be watched closely. Tricyclic antidepressant drugs, including amitriptyline, particularly when given in high doses, have been reported to produce arrhythmias, sinus tachycardia, and prolongation of the conduction time.

Pregnancy: There are no well-controlled studies in pregnant women; therefore, in administering the drug to pregnant patients or women who may become pregnant, the potential benefits must be weighed against the possible hazards to mother and child.

Lactation: Amitriptyline is detectable in breast milk. Because of the potential for serious adverse reactions in infants from amitriptyline, a decision should be made whether to discontinue nursing or discontinue the drug.

Children: In view of the lack of experience with the use of this drug in the treatment of depression in children, amitriptyline is not recommended for depressed patients under 12 years of age.

Precautions: The potency of amitriptyline is such that addition of other antidepressant drugs generally does not result in any additional therapeutic benefit. Untoward reactions have been reported after the combined use of antidepressant agents having varying modes of activity. Accordingly, combined use of amitriptyline and other antidepressant drugs should be undertaken only with due recognition of the possiblity of potentiation and with a thorough knowledge of the pharmacology of both drugs. There has been no reports of untoward events when patients receiving amitriptyline were changed immediately to protriptyline or vice versa. When amitriptyline is used to treat the depressive component of schizophrenia, activation or aggravation of existing psychotic manifestation may occur. Likewise, manic depressive patients may experience hypomanic or manic episodes and hyperactive or agitated patients may become overstimulated. Paranoid delusions, with or discontinuation of amitriptyline may be indicated and administration of a neuroleptic such as a phenothiazine, be considered under these circumstances.

Drug Interactions: Amitriptyline may block the antihypertensive action of guanethidine or similarly acting compounds. When amitriptyline is given with anticholinergic agents or sympathomimetic durgs, including epinephrine combined with local anesthetics, close supervision and careful adjustment of dosage are required. Paralytic ileus may occur in patients taking tricyclic antidepressants in combination with anticholinergic-type drugs. Since amitriptyline, in combination with anticholinergic type drugs, may give rise to paralytic ileus, particularly in elderly or hospitalized patients. Cimetidine is reported to reduce hepatic metabolism of certain tricyclic antidepressants. Amitriptyline may enhance the response to alcohol and the effects of barbiturates and other CNS depressants. Delirium has been reported with concurrent administration of amitriptyline and disulfiram. Hyperpyrexia has been reported when tricyclic antidepressants are administered with anticholinergic agents or with neuroleptic drugs, particularly during hot weather.

Adverse Reactions: Included in this listing which follows are a few adverse reactions which have not been reported with this specific drug. However, pharmacological similarities among the tricyclic antidepressant drugs require that each of the reactions be considered when amitriptyline is administered.

Neurological: Epileptiform seizures, coma, dizziness, tremors, numbness, tingling, paresthesias of the extremities, peripheral neuropathy, headache, ataxia, alteration in EEG patterns, extrapyramidal symptoms including abnormal involuntary movements and tardive dyskinesia, dysarthria, tinnitus, incoordination, and slurred speech.

Anticholinergic: Urinary retention, dilatation of the urinary tract, constipation, paralytic ileus, especially in the elderly, hyperpyrexia, dry mouth, blurred vision, disturbance of accommodation, increased intraocular pressure, precipitation of latent glaucoma, aggravation of existing glaucoma and mydriasis.

Cardiovascular: Quinidine-like effect and other non-specific ECG changes and changes in AV conduction, prolonged conduction time, asystole, hypotension, syncope, hypertension, palpitation, arrhythmias, heart block, ventricular tachycardia, fibrillation, myocardial infarction, stroke, unexpected death in patients with cardiovascular disorders.

Hematologic: Bone marrow depression, including agranulocytosis, leukopenia, eosinophilia, purpura, thromobocytopenia.

Allergic: Skin rash, urticaria, photosensitization, edema of the face and tongue, itching.

Gastrointestinal: Nausea, epigastric distress, heartburn, vomiting, hepatitis (including altered liver function and jaundice), anorexia, stomatitis, peculiar taste, diarrhea, parotid swelling, black tongue may occur.

Endocrine: Testicular swelling, gynecomastia and impotence in the male, breast enlargement and galactorrhea in the female, increased or decreased libido, elevation and lowering of blood sugar levels, syndrome of inappropriate ADH (antidiuretic hormone) secretion.

Miscellaneous: Weakness, increased perspiration, edema, urinary frequency, alopecia, increased appetite, weight gain, weight loss.

Symptoms And Treatment Of Overdose: Symptoms: High doses may cause temporary confusion, disturbed concentration, or transient visual hallucinations. Overdosage may cause drowsiness, hypothermia, tachycardia and other arrhythmic abnormalities, such as bundle branch block, ECG evidence of impaired conduction, congestive heart failure, disorders of ocular motility, convulsions, severe hypotension, stupor, coma, polyradiculoneuropathy and constipation. Other symptoms may be agitation, hyperactive reflexes, muscle rigidity, vomiting, hyperpyrexia. In patients with glaucoma, even average doses may precipitate an attack.

Treatment: Treatment is symptomatic and supportive. Cardiac arrhythmias and CNS involvement pose the greatest threat and may occur suddenly even when initial symptoms appear to be mild. Therefore, patients who may have ingested and overdosage of amitriptyline, particularly children, should be hospitalized and kept under close surveillance. Induced emesis and gastric lavage are recommended in the alert and conscious patient. Following gastric lavage, activated charcoal may be administered. Twenty to 30g of activated charcoal may be given every 4 to 6 hours during the first 24 to 48 hours after ingestion. It may be helpful to leave the tube in the stomach, with irrigation (with an electrolyte balanced fluid) and continual aspiration of stomach contents possibly promoting more rapid elimination of the drug from the body. If the patient is not alert, a cuffed endotracheal tube should be inserted before lavage is performed, and emesis should not be induced. An open airway should be maintained. Standard measures may be used to manage circulatory shock and metabolic acidosis. Norepinephrine or other pressor agents by i.v. drop infusion under continuous monitoring may be used if necessary. Failing respiration must be maintained by artificial means, but respiratory stimulants should not be used. Regulate body temperature. Hyperpyrexia should be controlled by external measures, such as ice packs and cooling sponge baths. Catheterization should be performed in the unconscious patient.

The room should be darkened, with a minimal amount of external stimulation, to reduce the tendency to convulsions. If convulsions occur, they should preferably be controlled by non-barbiturate sedatives, such as chlordiazepoxide or diazepam, or by an inhalation anesthetic (amitriptyline increases the CNS depressant but not the anticonvulsant action of barbiturates). Deaths by deliberate or accidental overdosage have occurred with this class of drugs. Since the propensity for suicide is high in depressed patients, a suicide attempt by other means may occur during the recovery phase. The possibility of simultaneous ingestion of other drugs should also be considered. Dialysis has not been found to be of value for intoxication by amitriptyline alone due to low plasma concentrations of the drug.

Dosage And Administration: Dosage should be initiated at a low level and increased gradually, noting carefully the clinical response and any evidence of intolerance. Hospitalized Patients: Severely ill or hospitalized patients may require 100mg a day initially. This can be increased gradually to 200mg a day if necessary. A small number of hospitalized patients may need as much as 300mg a day. Adolescent and Elderly Patients: Lower dosages are recommended for these patients. In those patients who may not tolerate higher doses, 50mg daily may be satisfactory. The dose may be administered in divided doses or as a single dose preferably in the evening or at bedtime.

Plasma Levels: Because of the wide variation in the absorption and distribution of tricyclic antidepressants in body fluids, it is difficult to directly correlate plasma levels may be useful in identifying patients who appear to have toxic effects and may have excessively high levels, or those in whom lack of absorption or non-compliance is suspected. Adjustments in dosage should be made according to the patient's clinical response and not on the basis of plasma levels.

Storage:
Store between 15-30°C.
Protect from heat, light and moisture.
Keep all medicines out of the reach of children.

Availability:
Amotrip: Each tablet contains Amitriptyline HCl B.P 25mg. Pack of 5 x 20's in blisters.

ایموٹرپ 25 ملی گرام

(ایمی ٹرپ ٹائیلین) بی پی

ہدایات: 15 سے 30 ڈگری سینٹی گریڈ پر رکھیں۔
گرمی، روشنی اور نمی سے بچائیں۔
تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

Manufactured by:
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