DOXETAR-25

(Doxepin Hydrochloride Capsules U.S.P)

DESCRIPTION

Doxetar (Doxepin) is a tricyclic antidepressant.

CLINICAL PHARMACOLOGY

The mechanism of action of Doxetar is not definitely known. It is neither a central nervous stimulant nor a MAO inhibitor. Like other tricyclic antidepressants, Doxepin too is a NA reuptake blocker. It is readily absorbed from GIT and extensively demethylated by first pass metabolism in the liver to its primary active metabolite, desmethyl doxepin. Doxetar is excreted in urine mainly in the form of its metabolite. Estimated plasma half-life ranges from 8-24 hours. It crosses the BBB and placental barrier.

INDICATIONS

Anxiety neurosis, anxiety associated with physical diseases, mixed anxiety-depression syndrome, neurotic depression unipolar depressive psychosis, depression of late-onset, manic-depressive psychosis-depressive type, alongwith methadone in cases of morphine addiction, anxiety-depression associated with chronic alcoholism, tension headache, old age problems with anxiety and/or depression.

CONTRAINDICATIONS

Patients with closed angle glaucoma and tendency towards urinary retention, patients with history of hypersensitivity to the drug.

PRECAUTIONS

Use with caution in patients who have experienced a recent myocardial infarction. Since suicide is an inherent risk in any depressed patient until significant improvement has occurred, patients should be closely supervised during early therapy. There is inadequate evidence of safety in human pregnancy but the drug has been widely used for many years without apparent ill consequences.

ADVERSE REACTIONS

Dryness of mouth, constipation, blurred vision, dizziness and drowsiness. These effects disappear with continuation of medication or symptomatic therapy.

DRUG INTERACTIONS

Combined use with other antidepressants, alcohol or antianxiety agents should be undertaken with due recognition of possibility of potentia-tion. Doxetar should not be given concurrently, or within two weeks of cessation of therapy with monoamine oxidase inhibitors. Cimetidine produces fluctuations in steady-state serum concentrations of Doxetar. Doxetar may decrease antihypertensive effect of debrisoquine, bethaniine, guanithidine and clonidine.

DOSAGE AND ADMINISTRATION

Dose may be varied according to severity of disease.

Mild to moderate illness: 25 mg t.i.d which may be varied at intervals, as per patient s response.

Severe illness: Initially, 50 mg t.i.d which may be increased to a maximum of 200 mg per day. For symptoms accompanying organic diseases lower doses may suffice.

OVERDOSAGE

Mild symptoms are drowsiness; stupor, blurred vision and dryness of mouth, while severe are bladder atony, paralytic ileus, hyperthermia (or hypothermia), hypertension, dilated pupils, hyperactive reflexes. Medical management of severe overdosage consists of aggressive supportive therapy. Use of activated charcoal has been recommended, as has been continuous gastric lavage with saline for 24 hours or more. Dialysis and forced diuresis generally are not of value because of high tissue and protein binding.

PRESENTATION

Doxetar-25 is available in blister strips of 10 capsules and bottle pack also, each hard gelatin capsule containing Doxepin hydrochloride U.S.P. equivalent to Doxepin 25 mg.

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Manufactured by :
TORRENT PHARMACEUTICALS LTD.
Indrad-382 721, Dist. Mehsana, INDIA.