ADNOR
Doxepin Hydrochloride

75 mg Capsule

Description
ADNOR (Doxepin Hydrochloride) is one of a class of psychotherapeutic agents known as dibenzoxepin tricyclic compounds. Chemically, Doxepin Hydrochloride is a dibenzoxepin derivative and is the first of a family of tricyclic psychotherapeutic agents.

Composition
ADNOR Capsule: Each capsule contains Doxepin Hydrochloride USP equivalent to 75 mg of Doxepin.

Indications and Uses
ADNOR (Doxepin Hydrochloride) is recommended for the treatment of
- Psychoneurotic patients with depression and/or anxiety.
- Depression and/or anxiety associated with alcoholism (not to be taken concomitantly with alcohol).
- Depression and/or anxiety associated with organic disease (the possibility of drug interaction should be considered if the patient is receiving other drugs concomitantly).
- Psychotic depressive disorders with associated anxiety including involutional depression and manic-depressive disorders.

Dosage and Administration
For most patients with illness of mild to moderate severity, a starting daily dose of 75 mg is recommended. Dosage may subsequently be increased or decreased at appropriate intervals and according to individual response. The usual optimum dose range is 75 mg/day to 150 mg/day.
In more severely ill patients, higher doses may be required with subsequent gradual increase to 300 mg/day if necessary. Additional therapeutic effect is rarely to be obtained by exceeding a dose of 300 mg/day.
In patients with very mild symptomatology or emotional symptoms accompanying organic disease, lower doses may suffice. Some of these patients have been controlled on doses as low as 25 to 50 mg/day.
The total daily dosage of Doxepin (as the Hydrochloride) may be given on a divided or once a day dosage schedule. If the once a day schedule is employed the maximum recommended dose is 150 mg/day. This dose may be given at bedtime. The 150 mg capsule strength is intended for maintenance therapy only and is not recommended for initiation of treatment.

Contraindications
Doxepin is contraindicated in individuals who have shown hypersensitivity to the drug. Possibility of cross sensitivity with other dibenzoxepines should be kept in mind.
Doxepin is contraindicated in patients with glaucoma or a tendency to urinary retention. These disorders should be ruled out, particularly in older patients.

Precautions
Patients, their families and their caregivers should be encouraged to be alert to the emergence of anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, mania, other unusual changes in behavior, worsening of depression, and suicidal ideation, especially early during antidepressant treatment and when the dose is adjusted up or down. Families and caregivers of patients should be advised to look for the emergence of such symptoms on a day to day basis, since changes may be abrupt. Such symptoms should be reported to the patient's prescriber or health professional, especially if they are severe, abrupt in onset, or were not part of the patient's presenting symptoms. Symptoms such as these may be associated with an increased risk for suicidal thinking and behavior and indicate a need for very close monitoring and possibly changes in the medication.

Pediatric Use
Safety and effectiveness in the pediatric population have not been established

Pregnancy and Lactation
Reproduction studies have been performed in rats, rabbits, monkeys and dogs and there was no evidence of harm to the animal foetus. The relevance to humans is not known. Since there is no experience in pregnant women who have received this drug, safety in pregnancy has not been established. There has been a report of apnea and drowsiness occurring in a nursing infant whose mother was taking Doxepin.

Side Effects
Nausea, vomiting, indigestion, taste disturbances, diarrhea, anorexia, dry mouth, blurred vision, constipation, drowsiness, confusion, disorientation, hallucinations, numbness, paresthesias, ataxia, extrapyramidal symptoms, seizures, tremor and urinary retention have been reported. Cardiovascular effects including hypotension, hypertension, and tachycardia have been reported occasionally. Skin rash, edema, photosensitization, and pruritus have occasionally occurred.Eosinophilia has been reported in a few patients. There have been occasional reports of bone marrow depression manifesting as agranulocytosis, leukopenia, thrombocytopenia, and purpura.Raised or lowered libido, testicular swelling, gynecomastia in males, enlargement of breasts and galactorrhea in the female, raising or lowering of blood sugar levels and syndrome of inappropriate antidiuretic hormone secretion have been reported with tricyclic administration. Dizziness, tinnitus, weight gain, sweating, chills, fatigue, weakness, flushing, jaundice, alopecia, headache, exacerbation of asthma, and hyperpyrexia (in association with chlorpromazine) have been occasionally observed as adverse effects.

How Supplied
ADNOR Capsule: Box containing 28's capsule in Alu-Alu pack.

Apex pharma®

Manufactured by
Apex Pharma Ltd.
Shafipur Gazipur