ANTIDEP

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

Abbreviated Prescribing information for ANTIDEP (Imipramine Hydrochloride 25mg and 75mg Tablet) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Tricyclic antidepressant. Noradrenaline (NA) and serotonin (5HT) re-uptake inhibitor.

INDICATION: Treatment of symptoms of depressive illness. Relief of nocturnal enuresis in children.

DOSAGE AND ADMINISTRATION: Adults: 25mg up to three times daily, increasing stepwise to 150-200mg daily. Maintenance dose: 50-100mg/day Elderly: initiated with 10mg daily, increased to 30-50mg daily. Children (for nocturnal enuresis only): Over 11 years: 50-75mg daily, 8 -11 years: 25- 50mg daily, 6 -7 years: 25mg daily. Not to be given to children under 6 years of age.

CONTRAINDICATION: Hypersensitivity to imipramine, any of the excipients in the tablets or cross-sensitivity to other tricyclic antidepressants of the dibenzazepine group, Any degree of heart block or cardiac arrhythmias; recent myocardial infarction, Severe liver disease, Porphyria, Narrow angle glaucoma, Urine retention, Mania, Concomitant treatment with selective, reversible MAO-A inhibitors, e.g. moclobemide, Children under six years of age.

WARNINGS & PRECAUTIONS: Suicide/suicidal thoughts or clinical worsening, risk of serotonin syndrome particularly with concomitant use of other serotonergic drugs or drugs that impair metabolism of serotonin, angle-closure glaucoma, activation of psychosis, photosensitization, elevation and lowering of blood sugar levels. Patients with any evidence of cardiovascular disease require cardiac surveillance at all dosage levels. Exercise caution while use in patients with impaired renal or hepatic function. As tricyclic antidepressants are known to lower the convulsion threshold, imipramine should be used with extreme caution in patients with epilepsy and other predisposing factors, e.g. brain damage of varying aetiology, concomitant use of neuroleptics, withdrawal from alcohol or drugs with anticonvulsive properties (e.g. benzodiazepines). Occurrence of seizures appears to be dose- dependent. Many patients with panic disorders experience intensified anxiety symptoms at the start of treatment with antidepressants. This paradoxical initial increase in anxiety is most pronounced during the first few days of treatment and generally subsides within two weeks. Caution is required in patients with hyperthyroidism or during concomitant treatment with thyroid preparations as aggravation of unwanted cardiac effects may occur. In predisposed and elderly patients, imipramine may, particularly at night, provoke pharmacogenic (delirious) psychoses, which disappear without treatment within a few days of withdrawing the drug. Agitation, confusion and postural hypotension may occur.Abrupt withdrawal should be avoided because of possible adverse reactions. Behavioural disturbances may occur in children receiving treatment with imipramine for the treatment of nocturnal enuresis.

DRUG INTERACTIONS: Interacts with hepatic enzyme inhibitors (e.g., cimetidine, fluoxetine), hepatic enzyme inducers (e.g., barbiturates, phenytoin), decongestants, local anesthetics, blood pressure lowering drugs, anticholinergic agents (including antiparkinsonism agents), CNS depressants and selective serotonin reuptake inhibitors (SSRIs), neuroleptics and adrenergic neuron blockers. MAO inhibitors (MAOIs): Imipramine should not be administered for at least three weeks after discontinuation of treatment with MAO inhibitors (there is a risk of severe symptoms such as hypertensive crisis, hyperpyrexia, myoclonus, agitation, seizures, delirium and coma). Selective serotonin reuptake inhibitors (SSRIs): Co-medication may lead to additive effects on the serotonergic system. Beta-blockers: Blood concentrations of imipramine may be increased by drugs such as labetalol and propranolol. The clinical importance of these interactions

is uncertain. Diuretics: Concurrent use of a tricyclic antidepressant and a diuretic may increase the risk of postural hypotension., Alpha2-adrenoceptor stimulants: concomitant use of apraclonidine or brimonidine should be avoided. Antiviral agents: Drugs such as ritonavir have been reported to increase plasma concentrations of antidepressant drugs, ritonavir (to treat HIV),buprenorphine/opioids .These medicines may interact with Imipramine tablets and you may experience symptoms of serotonin syndrome such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C.

ADVERSE REACTIONS: Orthostatic hypotension, hypertension, myocardial infarction, arrhythmias, heart block, ECG changes, precipitation of congestive heart failure, stroke, confusional states (especially in the elderly) with hallucinations, disorientation, delusions, anxiety, restlessness, agitation, insomnia and nightmares, hypomania, numbness, tingling, paresthesias of extremities, peripheral neuropathy, extrapyramidal symptoms, seizures, alterations in EEG patterns, tinnitus, dry mouth, associated sublingual adenitis, blurred vision, disturbances of accommodation, mydriasis, constipation, paralytic ileus, urinary retention, delayed micturition, dilation of the urinary tract, skin rash, petechiae, urticaria, itching, edema (general or of face and tongue), drug fever, cross-sensitivity with desipramine, bone marrow depression including agranulocytosis, eosinophilia, purpura, thrombocytopenia, nausea and vomiting, anorexia, epigastric distress, diarrhea, peculiar taste, stomatitis, abdominal cramps, black tongue, gynecomastia in the male, breast enlargement and galactorrhea in the female, increased or decreased libido, impotence, testicular swelling, inappropriate antidiuretic hormone (ADH) secretion syndrome, jaundice (simulating obstructive), weight gain or loss, perspiration, flushing, urinary frequency, drowsiness, dizziness, weakness and fatigue, headache, parotid swelling, alopecia, proneness to falling and withdrawal symptoms.

MARKETED BY:

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(Additional information is available on request)