AMITOR TAB

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

Abbreviated Prescribing information for AMITOR 75 TAB (Amitriptyline Hydrochloride Tablets 75 mg)
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Amitriptyline is a tricyclic antidepressant and an analgesic. It has marked anticholinergic and sedative properties. It prevents the re-uptake, and hence the inactivation of noradrenaline and serotonin at nerve terminals. Reuptake prevention of these monoamine neurotransmitters potentiate their action in the brain. This appears to be associated with the antidepressant activity. The mechanism of action also includes ion-channel blocking effects on sodium, potassium and NMDA channel at both central and spinal cord level. The noradrenaline, sodium and the NMDA effects are mechanisms known to be involved in the maintenance of neuropathic pain, chronic tension type headache prophylaxis and migraine prophylaxis. The pain reducing effect of amitriptyline is not linked to its anti-depressive properties. Tricyclic antidepressants possess affinity for muscarinic and histamine H_1 receptors to varying degrees.

INDICATIONS: For the relief of symptoms of depression. Endogenous depression is more likely to be alleviated than are other depressive states.

DOSAGE AND ADMINISTRATION: Dosage should be initiated at a low level and increased gradually, noting carefully the clinical response and any evidence of intolerance. For outpatients, 75 mg of amitriptyline HCl a day in divided doses is usually satisfactory.

CONTRAINDICATION: Hypersensitivity to the active substance or to any of the excipients. Recent myocardial infarction. Any degree of heart block or disorders of cardiac rhythm and coronary artery insufficiency. Concomitant treatment with MAOIs (monoamine oxidase inhibitors) is contra-indicated. Simultaneous administration of amitriptyline and MAOIs may cause serotonin syndrome (a combination of symptoms, possibly including agitation, confusion, tremor, myoclonus and hyperthermia). Treatment with amitriptyline may be instituted 14 days after discontinuation of irreversible non-selective MAOIs and minimum one day after discontinuation of the reversible moclobemide. Treatment with MAOIs may be introduced 14 days after discontinuation of amitriptyline. Severe liver disease. In children under 6 years of age.

WARNINGS & PRECAUTIONS: Cardiac arrhythmias and severe hypotension are likely to occur with high dosage. They may also occur in patients with pre-existing heart disease taking normal dosage. QT interval prolongation: Elderly patients are particularly susceptible to orthostatic hypotension. Caution is advised in patients with significant bradycardia, in patients with uncompensated heart failure, or in patients concurrently taking QT-prolonging drugs, Suicide/suicidal thoughts: Depression is associated with an increased risk of suicidal thoughts, self-harm and suicide (suicide-related events). In manic-depressives, a shift towards the manic phase may occur; should the patient enter a manic phase amitriptyline should be discontinued. As described for other psychotropics, amitriptyline may modify insulin and glucose responses calling for adjustment of the antidiabetic therapy in diabetic patients; in addition, the depressive illness itself may affect patients' glucose balance. Hyperpyrexia has been reported with tricyclic antidepressants when administered with anticholinergic or with neuroleptic medications, especially in hot weather. , Nocturnal enuresis: Amitriptyline for enuresis should not be combined with an anticholinergic drug, Paediatric population: Long-term safety data in children and adolescents concerning growth, maturation and cognitive and behavioral development are not available. Amitriptyline should be used with caution in patients receiving SSRIs, Excipient Warnings: This product contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

DRUG INTERACTIONS: Potential for amitriptyline to affect other medicinal products: Contraindicated combinations: MAOIs (non-selective as well as selective A (moclobemide) and B (selegiline)) - risk of "serotonin syndrome". Combinations that are not recommended: *Sympathomimetic agents:* Adrenaline, Ephedrine, *Adrenergic neurone blockers:* Guanethidine, Betanidine, *Anticholinergic agents*: Tricyclic antidepressants, *Drugs which prolong the QT-interval:* Quinidine, Astemizole and Terfenadine. *Thioridazine, Tramadol, Antifungals*: Fluconazole and Terbinafine. *CNS depressants.* **Potential of other medicinal products to affect amitriptyline:** *CYP2D6 inhibitors, Other Cytochrome P450 inhibitors:* Cimetidine, methylphenidate, *Tricyclic antidepressants and neuroleptics, Cytochrome P450 inducers:* Oral contraceptives, rifampicin. *Ethanol.*

ADVERSE REACTIONS: Aggression, Somnolence, Tremor, Dizziness, Headache, Drowsiness, Speech Disorder (Dysarthria), Accommodation Disorder, Palpitations, Tachycardia, Orthostatic Hypotension, Congested Nose, Congested Nose, Hyperhidrosis, Weight Increased, Confusional State, Libido Decreased, Agitation, Disturbance In Attention, Dysgeusia. Paresthesia, Ataxia, Mydriasis, Atrioventricular Block, Bundle Branch Block, Micturition Disorders, Fatigue, Feeling Thirst, Electrocardiogram Abnormal, Electrocardiogram QT Prolonged, Electrocardiogram QRS Complex Prolonged, Hyponatremia.

MARKETED BY:

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IN/ AMITOR 10,25,75mg/AUG-24/01/ABPI

(Additional information is available on request)