MILNACE

To be sold by retail on the prescription of a Psychiatrist only

Abbreviated Prescribing information for Milnace (Milnacipran Hydrochloride Tablets 25 mg & 50 mg) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Milnacipran is a dual inhibitor of serotonin and norepinephrine re-uptake.

INDICATION: It is indicated in treatment of major depressive episodes in adults.

DOSAGE AND ADMINISTRATION: Usual starting dose is 50 mg once daily or in divided dose. Recommended dosage is 100 mg a day in two divided 50 mg doses, one tablet morning and evening preferably during meals.

CONTRAINDICATION: Milnace should never be used in children under 15 years of age, association with non-selective MAO inhibitors (B selective MAO inhibitors, digitalis and 5 HT₁D agonists), lactation, with epinephrine and nor-epinephrine by parenteral route, clonidine and related compounds, genito – urinary disorders and pregnancy. It is also contraindicated in the patients with known hypersensitivity to milnacipran and any of the ingredients of the tablet.

WARNINGS & PRECAUTIONS: Suicide attempts in patients suffering from depression persist as like other antidepressant. Patients with insomnia or nervousness may require transient symptomatic therapy. The treatment should be discontinued, if a patient experiences a switch into frank mania. It is recommended to avoid alcohol intake. In patients with renal failure dosage may have to be reduced. Milnacipran can slightly increase heart rate in some patients hence clinical monitoring is recommended. It should be use cautiously in patients with narrow-angle glaucoma, epilepsy, bleeding abnormality and the patients taking anticoagulants.

DRUG INTERACTIONS: With non-selective MAO inhibitors: Risk of a serotoninergic syndrome, With selective MAO-A inhibitors: Risk of development of a serotoninergic syndrome, With selective MAO-B inhibitors: Risk of paroxystic hypertension, With 5 HT1D agonists: Risk of hypertension, coronary artery vasoconstriction by additive serotoninergic effects, With digitalis: Risk of potentiation of haemodynamic effects, With clonidine and related compounds it may inhibit its antihypertensive effect.

ADVERSE REACTIONS: Depressive episode, vertigo, excessive sweating, anxiety, hot flush, and dysuria, nausea, vomiting, dry mouth, constipation, tremor, palpitations, agitation, headache, urticaria, rash sometimes maculo-papular or erythematous and pruritus, incidence of cardiovascular adverse events like hypertension, hypotension, postural hypotension, tachycardia and palpitations, serotoninergic syndrome, moderate elevation of transaminases, urinary retention, convulsions, testicular pain, ejaculation disorders, hyponatremia, ecchymosis, mood switch, with episodes of mania, reactivation of a delirium in psychotic patients and paroxystic symptoms of anxiety.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD. Torrent House, Off Ashram Road, Ahmedabad-380 009, INDIA

IN/ MILNACE 25,50mg/Jun-15/01/AbPI (Additional information is available on request)