SYMBAL

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

Abbreviated Prescribing information for SYMBAL (Duloxetine Tablets 20/30/40/60 mg) [Please refer the complete prescribing information available at www.torrentpharma.com

PHARMACOLOGICAL PROPERTIES: - Duloxetine hydrochloride is a selective serotonin and norepinephrine reuptake inhibitor (SSNRI) for oral administration.

INDICATION: Major depressive episodes, moderate to severe stress urinary incontinence in women and diabetic peripheral neuropathic pain in adults.

DOSAGE AND ADMINISTRATION: Major depressive episode: Administered as a total dose of 40mg/day (given either once a day or as 20mg BID) to 60mg/day (given either once a day or as 30mg BID) without regard to meals. Diabetic peripheral neuropathic pain in adults: 60mg daily, with or without food. It can be uptitrated to 120mg daily in evenly divided doses. Moderate to severe stress urinary incontinence: 40mg twice daily, without regard to meals.

CONTRAINDICATION: In patients who receive monoamine oxidase inhibitors (MAOIs) or who have discontinued within 14 days, MAOIs such as linezolid or intravenous methylene blue, fluvoxamine, ciprofloxacin or enoxacin (i.e., potent CYP1A2 inhibitors), and in patients with hypersensitivity to the active substance or to any of the excipients, liver disease resulting in hepatic impairment, severe renal impairment (creatinine clearance <30 ml/min), uncontrolled hypertension and uncontrolled narrow angle glaucoma.

WARNINGS & PRECAUTIONS: Suicidal thoughts and behaviors in adolescents and young adults, a major depressive episode may be the initial presentation of bipolar disorder. it is generally believed (though not established in controlled trials) that treating such an episode with an antidepressant alone may increase the likelihood of precipitation of a mixed/manic episode in patients at risk for bipolar disorder, hepatotoxicity, orthostatic hypotension and syncope, serotonin syndrome, abnormal bleeding, severe skin reactions including erythema multiforme and Stevens-Johnson Syndrome (SJS), discontinuation symptoms, activation of mania/hypomania, angle-closure glaucoma and should be prescribed with care in patients with a history of a seizure disorder,

DRUG INTERACTIONS: CYP1A2 and CYP2D6 inhibitors, drugs that interfere with hemostasis (e.g., NSAIDs, aspirin, and warfarin)**,** drugs that affect gastric acidity**,** plasma tricyclic antidepressants (TCA) concentrations may need to be monitored and the dose of the TCA may need to be reduced if a TCA is co-administered with duloxetine because of the risk of serious ventricular arrhythmias and sudden death potentially associated with elevated plasma levels of thioridazine, duloxetine and thioridazine should not be co-administered. Hyponatremia may occur as a result of treatment with SSRIS and SNRIS, including duloxetine. It should not be prescribed for patients with substantial alcohol use, in patients with hepatic insufficiency and alongwith CNS acting drugs. Urinary hesitation and retention may occur as duloxetine is in a class of drugs known to affect urethral resistance.

ADVERSE REACTIONS: Nausea, vomiting, dizziness, somnolence, asthenia**,** dry mouth, constipation, decreased appetite, hyperhidrosis, anaphylactic reaction, aggression and anger (particularly early in treatment or after treatment discontinuation), angioneurotic edema, extrapyramidal disorder, galactorrhea, gynecological bleeding, hallucinations, hyperglycemia, hyperprolactinemia, hypersensitivity, hypertensive crisis, muscle spasm, rash, restless legs syndrome, seizures upon treatment discontinuation, supraventricular arrhythmia, tinnitus (upon treatment discontinuation), trismus, and urticaria, palpitations, myocardial infarction and tachycardia, vertigo, ear pain and tinnitus, hypothyroidism, vision blurred, diplopia, and visual disturbance, flatulence, eructation, gastritis, halitosis, and stomatitis, chills/rigors, weight increased, musculoskeletal pain, dysgeusia, lethargy, abnormal dreams and sleep disorder and anorgasmia.

MARKETED BY:

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IN/ SYMBAL 20,30,40,60 mg /Feb-15/01/AbPI
(Additional information is available on request)