VENLIFT OD

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

Abbreviated Prescribing information for Venlift OD (Venlafaxine hydrochloride 37.5, 75 and 150mg Extended-Release Capsules) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Venlift OD is an extended-release capsule for oral administration that contains venlafaxine hydrochloride, a structurally novel antidepressant. **INDICATIONS:** Venlift OD-37.5 mg and 75 mg for Major depression, Venlift OD-150 mg for Generalised anxiety disorders.

CONTRAINDICATION: Hypersensitivity to venlafaxine hydrochloride or to any excipients in the formulation. The use of Monoamine Oxidase Inhibitors (MAOIs) with venlafaxine hydrochloride is contraindicated because of an increased risk of serotonin syndrome.

WARNINGS & PRECAUTIONS: Clinical Worsening and Suicide Risk: Patients with major depressive disorder (MDD) may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior. It is generally believed that treating depressive episode with an antidepressant alone may increase the likelihood of precipitation of a mixed/manic episode in patients at risk for bipolar disorder. The development of a potentially life-threatening serotonin syndrome has been reported. Angle-Closure Glaucoma: The pupillary dilation that occurs following venlafaxine hydrochloride may trigger an angle closure attack in a patient. Venlafaxine hydrochloride treatment is associated with sustained hypertension and elevations in systolic and diastolic blood pressure. Discontinuation symptoms include agitation, anorexia, anxiety, confusion, impaired coordination and balance, diarrhea, dizziness, dry mouth, dysphoric mood, fasciculation, fatigue, flu-like symptoms, headaches, hypomania, insomnia, nausea, nervousness, nightmares, sensory disturbances (including shock-like electrical sensations), somnolence, sweating, tremor, vertigo, and vomiting. Changes in weight, height and appetite are reported. Hypomania, hypernatremia and seizures were also reported. Venlafaxine may increase the risk of bleeding events. Concomitant use of aspirin, nonsteroidal anti-inflammatory drugs, warfarin, and other anti-coagulants or other drugs known to affect platelet function may add to this risk. Clinically relevant increases in serum cholesterol were recorded. The mean change from baseline in corrected QT interval (QTc) for venlafaxine-treated patients was increased. Patients should be advised to avoid alcohol while taking venlafaxine, and also to notify their physician if they become pregnant or intend to become pregnant during therapy or they are breast-feeding an infant and if they develop a rash, hives, or a related allergic phenomenon.

DRUG INTERACTIONS: Cimetidine, haloperidol, alcohol, drugs that Interfere with Hemostasis (e.g., NSAIDs, Aspirin, and Warfarin)**,** drugs that inhibit cytochrome P450 isoenzymes, risperidone, metoprolol, imipramine and triptans.

ADVERSE REACTIONS: Agranulocytosis, anaphylaxis, angioedema, aplastic anemia, catatonia, congenital anomalies, impaired coordination and balance, CPK increased, deep vein thrombophlebitis, delirium, EKG abnormalities such as QT prolongation, cardiac arrhythmias including atrial fibrillation, supraventricular tachycardia, ventricular extrasystoles, ventricular fibrillation, ventricular tachycardia, torsade de pointes, toxic epidermal necrolysis/Stevens-Johnson Syndrome, erythema multiforme, extrapyramidal symptoms (including dyskinesia and tardive dyskinesia), hemorrhage (including eye and gastrointestinal bleeding), hepatic events (including GGT elevation; abnormalities of unspecified liver function tests; liver damage, necrosis, or failure; and fatty liver), interstitial lung disease, involuntary movements, LDH increased, neutropenia, night sweats, pancreatitis, pancytopenia, panic, prolactin increased, renal failure, rhabdomyolysis, shock-like electrical sensations or tinnitus and syndrome of inappropriate antidiuretic hormone secretion (usually in the elderly).

MARKETED BY:

torrent PHARMA

TORRENT PHARMACEUTICALS LTD.
Torrent House, Off Ashram Road,
Ahmedabad-380 009, INDIA
IN/ Venlift OD/37.5, 75, 150 mg/Jul-2015/01/AbPI
(Additional information is available on request)