PRODUCT NAME	:	Venlift ER	**COUNTRY :** Malaysia	**LOCATION :** Indrad	**Supersedes A/W No.:**		
ITEM / PACK	:	Insert	**NO. OF COLORS:** 1	**REMARK :**			
DESIGN STYLE	:	Front / Back	**PANTONE SHADE NOS.:**	**SUBSTRATE :**			
CODE	:	xxxxxxxx-5253	Black	**Activities**	**Department**	**Name**	**Date**
DIMENSIONS (MM)	:	180 x 330		Prepared By	**Pkg.Dev**		
ART WORK SIZE	:	S/S		Reviewed By	**Pkg.Dev**		
DATE	:	31-03-2022		Approved By	**Quality**		

xxxxxxxx-5253

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

VENLIFT ER 37.5 MG CAPSULES
VENLIFT ER 75 MG CAPSULES
VENLIFT ER 150 MG CAPSULES

(Venlafaxine Extended Release Capsules)

PRODUCT NAME
VENLIFT ER 37.5 MG CAPSULES VENLIFT ER 75 MG CAPSULES
VENLIFT ER 150 MG CAPSULES
NAME AND STRENGTH OF ACTIVE SUBSTANCE(S)
VENLIFT ER 37.5 MG CAPSULES
VENLIFT ER 75 MG CAPSULES
VENLIFT ER 150 MG CAPSULES
Each hard gelatin capsule contains:
Venlafaxine hydrochloride Ph. Eur.
equivalent to Venlafaxine 37.5/75/150 mg
(In the form of extended release pellets)
Approved colors used in hard gelatin capsule shell
Gelatin of Bovine origin
PRODUCT DESCRIPTION
VENLIFT ER 37.5 MG CAPSULES: Size "4" Peach/Translucent Peach, hard gelatin capsules, containing white to off-white pellets.
VENLIFT ER 75 MG CAPSULES: Size "2", Yellow/translucent yellow, hard gelatin capsules, containing white to off-white pellets.
VENLIFT ER 150 MG CAPSULES: Size "0", Orange/translucent orange, hard gelatin capsules, containing white to off-white pellets.
DOSAGE FORM
Hard Gelatin Capsule
CLINICAL PHARMACOLOGY
Pharmacodynamics
The mechanism of the antidepressant action of venlafaxine in humans is believed to be associated with its potentiation of neurotransmitter activity in the central nervous system. Preclinical studies have reported that venlafaxine and its major metabolite, O-Desmethyl venlafaxine (ODV), are potent inhibitors of neuronal serotonin and norepinephrine reuptake, and weak inhibitors of dopamine reuptake. Animal studies reported that tricyclic antidepressants may reduce β-adrenergic receptor responsiveness following chronic administration. In contrast, venlafaxine and O-Desmethyl venlafaxine reduce β-adrenergic responsiveness after both acute (single dose) and chronic administration. These results may predict a more rapid onset of clinical activity for venlafaxine. Venlafaxine and its major metabolite appear to be equipotent with respect to their overall action on neurotransmitter reuptake and receptor binding.
Pharmacokinetics
Venlafaxine is readily absorbed from the gastrointestinal tract. After oral doses it undergoes extensive first pass metabolism in the liver mainly to the active metabolite O- desmethylvenlafaxine; formation of O-desmethylvenlafaxine is mediated by the cytochrome P450 isoenzyme CYP2D6. The isoenzyme CYP3A4 is also involved in the metabolism of venlafaxine. Other metabolites include N-desmethyl venlafaxine and N,O-didesmethylvenlafaxine. Peak plasma concentrations of venlafaxine and O-desmethylvenlafaxine appear about 2 and 4 hours after a dose, respectively. Venlafaxine is 27% and O-desmethylvenlafaxine 30% bound to plasma proteins. The mean elimination halflife of Venlafaxine and O-desmethylvenlafaxine is about 5 and 11 hours, respectively. Venlafaxine is excreted mainly in the urine, mainly in the form of its metabolites, either free or in conjugated form; about 2% is excreted in the faeces. Venlafaxine and O-desmethyl venlafaxine have been detected in amniotic fluid and umbilical cord blood, and are distributed into breast milk
Effects on Food: Food has no significant effect on the absorption of venlafaxine or the formation of O-Desmethyl venlafaxine.
Patients with Hepatic impairment: The pharmacokinetic disposition of venlafaxine and O- Desmethyl venlafaxine are significantly altered in some patients with compensated hepatic cirrhosis (moderate hepatic impairment) following oral administration of single- dose venlafaxine.
Patients with Renal Impairment: Venlafaxine and O-Desmethyl venlafaxine elimination half- lives increase with the degree of impairment in renal function.
Age and Gender: Plasma levels of either venlafaxine or O-Desmethyl venlafaxine were unaltered by age or gender differences.
INDICATION
Venlift ER is indicated for the treatment of depression, including depression with associated anxiety, in hospitalized patients.
Treatment of anxiety or Generalized Anxiety Disorder (GAD), including long-term treatment. For prevention of relapse of an episode of depression or for prevention of the recurrence of new depressive episodes.
Venlift ER is indicated for the treatment of Social Anxiety Disorder, also known as Social Phobia, as defined in DSM-IV.
Social Anxiety Disorder (DSM-IV) is characterized by a marked and persistent fear of 1 or more social or performance situations in which the person is exposed to unfamiliar people or to possible scrutiny by others. Exposure to the feared situation almost invariably provokes anxiety, which may approach the intensity of a panic attack. The feared situations are avoided or endured with intense anxiety or distress. The avoidance, anxious anticipation, or distress in the feared situation(s) interferes significantly with the person's normal routine, occupational or academic functioning, or social activities or relationships, or there is a marked distress about having the phobias. Lesser degrees of performance anxiety or shyness generally do not require psychopharmacological treatment.
Panic disorder, including prevention of relapse.
RECOMMENDED DOSAGE AND MODE OF ADMINISTRATION
General Recommendation
It is recommended that venlafaxine extended-release capsules be taken with food, at approximately the same time each day. Capsules must be swallowed whole with fluid and not divided, crushed, chewed, or dissolved, or it may be administered by carefully opening the capsule and sprinkling the entire contents on a spoonful of applesauce. This drug/food mixture should be swallowed immediately without chewing and followed with a glass of water to ensure complete swallowing of the pellets.
With the exception of patients with SAD, patients not responding to the 75 mg/day dose may benefit from dose increases in increments of up to 75 mg/day to a maximum of 225 mg/day. Extended-release venlafaxine dosage increases can be made at intervals of 2 weeks or more, but not less than 4 days.
Patients treated with venlafaxine immediate-release tablets may be switched to venlafaxine extended-release capsules at the nearest equivalent daily dosage. For example, venlafaxine immediate-release tablets 37.5 mg twice daily may be switched to venlafaxine extended-release capsules 75 mg once daily. Individual dosage adjustments may be necessary.
Major Depressive Disorder
The recommended starting dose of extended-release venlafaxine is 75 mg given once daily.
Patients not responding to the initial 75 mg/day dose may benefit from dose increases to a maximum 225 mg/day.
The venlafaxine dose can be titrated up to 225 mg/day in moderately depressed patients and 375 mg/day for severely depressed patients.
Generalized Anxiety Disorder
The recommended starting dose for extended-release venlafaxine is 75 mg per day given once daily. Patients not responding to the initial 75 mg/day dose may benefit from dose increases to a maximum of 225 mg/day.
Social Anxiety Disorder
The recommended starting dose for extended-release venlafaxine is 75 mg/day, given once daily. There is no evidence that higher doses confer any additional benefit.
Panic Disorder
It is recommended that a dose of 37.5 mg/day of venlafaxine be used for 7 days. Dosage should then be increased to 75 mg/day. Patients not responding to the 75 mg/day dose may benefit from dose increases to a maximum of 225 mg/day.
Discontinuing Venlafaxine
Dose tapering is recommended whenever possible when discontinuing venlafaxine therapy. The period required for tapering may depend on the dose, duration of therapy, and the individual patient.
Use in Patients with Renal Impairment
The total daily dose of venlafaxine should be reduced by 25% to 50% for patients with renal impairment with a glomerular filtration rate (GFR) of 10 to 70 mL/min.
The total daily dose of venlafaxine should be reduced by 50% in hemodialysis patients. Because of individual variability in clearance in these patients, individualization of dosage may be desirable.
Use in Patients with Hepatic Impairment
The total daily dose of venlafaxine should be reduced by 50% in patients with mild to moderate hepatic impairment. Reductions of more than 50% may be appropriate for some patients. Because of individual variability in clearance in these patients, individualization of dosage may be desirable.
Use in Children and Adolescent
There is insufficient experience with the use of venlafaxine in patients less than 18 years of age.
Use in Elderly Patients
No specific dosage adjustments of venlafaxine are recommended based on patient age.
CONTRAINDICATIONS
Hypersensitivity to venlafaxine or any excipients in the formulation.
Concomitant use of venlafaxine and any monoamine oxidase inhibitor (MAOI). Venlafaxine must not be initiated for at least 14 days after discontinuation of treatment with a MAOI; a shorter interval may be justified in the case of a reversible MAOI (see prescribing information of the reversible MAOI). Venlafaxine must be discontinued for at least 7 days before starting treatment with any MAOI.
WARNINGS AND PRECAUTIONS
Suicide/suicidal thoughts or clinical worsening
Depression is associated with an increased risk of suicidal thoughts, self-harm and suicide (suicide- related events). This risk persists until significant remission occurs. As improvement may not occur during the first few weeks or more of treatment, patients should be closely monitored until such improvement occurs. It is general clinical experience that the risk of suicide may increase in the early stages of recovery.
Other psychiatric conditions for which venlafaxine is prescribed can also be associated with an increased risk of suicide-related events. In addition, these conditions may be co-morbid with major depressive disorder. The same precautions observed when treating patients with major depressive disorder should therefore be observed when treating patients with other psychiatric disorders.
Patients with a history of suicide-related events, or those exhibiting a significant degree of suicidal ideation prior to commencement of treatment, are known to be at greater risk of suicidal thoughts or suicide attempts, and should receive careful monitoring during treatment.
Close supervision of patients, and in particular those at high risk, should accompany drug therapy, especially in early treatment and following dose changes. Patients (and caregivers of patients) should be alerted about the need to monitor for any clinical worsening, suicidal behaviour or thoughts and unusual changes in behaviour, and to seek medical advice immediately if these symptoms present.
Use in children and adolescents under 18 years of age
Venlafaxine extended-release should not be used in the treatment of children and adolescents under the age of 18 years. Suicide-related behaviours (suicide attempt and suicidal thoughts) and hostility (predominantly aggression, oppositional behaviour and anger) were more frequently reported among children and adolescents treated with antidepressants. If, based on clinical need, a decision to treat is nevertheless taken, the patient should be carefully monitored for the appearance of suicidal symptoms. In addition, long-term safety data in children and adolescents concerning growth, maturation and cognitive and behavioural development are lacking.
Serotonin syndrome
As with other serotonergic agents, serotonin syndrome, a potentially life threatening condition may occur with venlafaxine treatment, particularly with concomitant use of other agents that may affect the serotonergic neurotransmitter system (including triptans, SSRIs, SNRIs, lithium, sibutramine, St.John's Wort [Hypericum perforatum], fentanyl and its analogues, tramadol, dextromethorphan, tapentadol, pethidine, methadone and pentazocine), with medicinal agents that impair metabolism of serotonin such as MAOIs e.g. methylene blue, with serotonin precursors (such as tryptophan supplements) or with antipsychotics or other dopamine antagonists.
Serotonin syndrome symptoms may include mental status changes (e.g., agitation, hallucinations, coma), autonomic instability (e.g., tachycardia, labile blood pressure, hyperthermia), neuromuscular aberrations (e.g., hyperreflexia, incoordination) and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhoea). Serotonin syndrome in its most severe form, can resemble NMS, which includes hyperthermia, muscle rigidity, autonomic instability with possible rapid fluctuation of vital signs and mental status changes.
If concomitant treatment with venlafaxine and other agents that may affect the serotonergic and/or dopaminergic neurotransmitter systems is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose increases.
The concomitant use of venlafaxine with serotonin precursors (such as tryptophan supplements) is not recommended.
Narrow-angle glaucoma
Mydriasis may occur in association with venlafaxine. It is recommended that patients with raised intraocular pressure or patients at risk for acute narrow-angle glaucoma (angle-closure glaucoma) be closely monitored.
Blood pressure
Dose-related increases in blood pressure have been commonly reported with venlafaxine. In some cases, severely elevated blood pressure requiring immediate treatment has been reported in postmarketing experience. All patients should be carefully screened for high blood pressure and pre-existing hypertension should be controlled before initation of treatment. Blood pressure should be reviewed periodically, after initiation of treatment and after dose increases. Caution should be exercised in patients whose underlying conditions might be compromised by increases in blood pressure, e.g., those with impaired cardiac function.
Heart rate
Increases in heart rate can occur, particularly with higher doses. Caution should be exercised in patients whose underlying conditions might be compromised by increases in heart rate.
Cardiac disease and risk of arrhythmia
Venlafaxine has not been reported in patients with a recent history of myocardial infarction or unstable heart disease. Therefore, it should be used with caution in these patients.
In postmarketing experience, fatal cardiac arrhythmias have been reported with the use of venlafaxine, especially in overdose. The balance of risks and benefits should be considered before prescribing venlafaxine to patients at high risk of serious cardiac arrhythmia.
Convulsions
Convulsions may occur with venlafaxine therapy. As with all antidepressants, venlafaxine should be introduced with caution in patients with a history of convulsions, and concerned patients should be closely monitored. Treatment should be discontinued in any patient who develops seizures.
Hyponatraemia
Cases of hyponatraemia and/or the Syndrome of Inappropriate Antidiuretic Hormone (SIADH) secretion may occur with venlafaxine. This has most frequently been reported in volume-depleted or dehydrated patients. Elderly patients, patients taking diuretics, and patients who are otherwise volume-depleted may be at greater risk for this event.
Abnormal bleeding
Medicinal products that inhibit serotonin uptake may lead to reduced platelet function. Bleeding events related to SSRI and SNRI use have ranged from ecchymoses, hematomas, epistaxis, and petechiae to gastrointestinal and life-threatening haemorrhages. The risk of haemorrhage may be increased in patients taking venlafaxine. As with other serotonin-reuptake inhibitors, venlafaxine should be used cautiously in patients predisposed to bleeding, including patients on anticoagulants and platelet inhibitors.
Serum cholesterol
Measurement of serum cholesterol levels should be considered during long-term treatment.
Co-administration with weight loss agents
The safety and efficacy of venlafaxine therapy in combination with weight loss agents, including phentermine, have not been reported. Co-administration of venlafaxine and weight loss agents is not recommended. Venlafaxine is not indicated for weight loss alone or in combination with other products.
Mania/hypomania
Mania/hypomania may occur in a small proportion of patients with mood disorders who have received antidepressants, including venlafaxine. As with other antidepressants, venlafaxine should be used cautiously in patients with a history or family history of bipolar disorder.
Aggression
Aggression may occur in a small number of patients who have received antidepressants, including venlafaxine. This has been reported under initiation, dose changes and discontinuation of treatment.
As with other antidepressants, venlafaxine should be used cautiously in patients with a history of aggression.
Discontinuation of treatment
Withdrawal symptoms, when treatment is discontinued, are common, particularly if discontinuation is abrupt.
The risk of withdrawal symptoms may be dependent on several factors, including the duration and dose of therapy and the rate of dose reduction. Dizziness, sensory disturbances (including paraesthesia), sleep disturbances (including insomnia and intense dreams), agitation or anxiety, nausea and/or vomiting, tremor and headache are the most commonly reported reactions. Generally, these symptoms are mild to moderate; however, in some patients they may be severe in intensity. They usually occur within the first few days of discontinuing treatment, but there have been very rare reports of such symptoms in patients who have inadvertently missed a dose. Generally, these symptoms are self-limiting and usually resolve within 2 weeks, though in some individuals they may be prolonged (2-3 months or more). It is therefore advised that venlafaxine should be gradually tapered when discontinuing treatment over a period of several weeks or months, according to the patient's needs.
Akathisia/psychomotor restlessness
The use of venlafaxine has been associated with the development of akathisia, characterised by a subjectively unpleasant or distressing restlessness and need to move often accompanied by an inability to sit or stand still. This is most likely to occur within the first few weeks of treatment. In patients who develop these symptoms, increasing the dose may be detrimental.
Dry mouth
This may increase the risk of caries, and patients should be advised upon the importance of dental hygiene.
Diabetes
In patients with diabetes, treatment with an SSRI or venlafaxine may alter glycaemic control. Insulin and/or oral antidiabetic dosage may need to be adjusted.
Drug-Laboratory Test Interactions
False-positive urine immunoassay screening tests for phencyclidine (PCP) and amphetamine have been reported in patients taking venlafaxine. This is due to lack of specificity of the screening tests. False positive test results may be expected for several days following discontinuation of venlafaxine therapy. Confirmatory tests, such as gas chromatography/mass spectrometry, will distinguish venlafaxine from PCP and amphetamine.
INTERACTIONS WITH OTHER MEDICAMENTS
Monoamine Oxidase Inhibitors (MAOI)
Serious and potentially life-threatening reactions can develop if venlafaxine and MAOIs (isocarboxazid, phenelzine, tranylcypromine) are given concurrently, or even sequentially if insufficient time is left in between.
CNS Active Drugs
Caution is advised when venlafaxine is taken in combination with other CNS-active drugs.
Serotonin Syndrome
As with other serotonergic agents, serotonin syndrome, a potentially life threatening condition, may occur with venlafaxine treatment, particularly with concomitant use of other agents that may affect the serotonergic neurotransmitter system including triptans, SSRIs, other SNRIs, linezolid [an antibiotic which is a reversible non-selective MAOI], lithium, sibutramine, tramadol, or St. John's Wort [Hypericum perforatum], with drugs which impair metabolism of serotonin (including MAOIs) or with serotonin precursors (such as tryptophan supplements). Serotonin syndrome symptoms may include mental status changes, autonomic instability, neuromuscular aberrations and/ or gastrointestinal symptoms.
If concomitant treatment of venlafaxine with an SSRI, an SNRI or a 5-hydroxytryptamine receptor agonist (triptan) is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose increases. The concomitant use of venlafaxine with serotonin precursors (such as tryptophan supplements) is not recommended.
Indinavir
Venlafaxine lowered indinavir levels.
Warfarin
Potentiation of anticoagulant effects may occur in patients taking warfarin following the addition of venlafaxine.
Ethanol
As with all CNS active drugs, patients should be advised to avoid alcohol consumption while taking venlafaxine.
Haloperidol
Venlafaxine can increase the serum level of haloperidol. This should be taken into account in patients treated with haloperidol and venlafaxine concomitantly
Cimetidine
Cimetidine may increase Venlafaxine plasma levels, which may lead to an increase in their adverse effects.
Tricyclic antidepressants
Venlafaxine can cause a marked increase in the antimuscarinic adverse effects of clomipramine, desipramine and nortriptyline.
Ketoconazole
Concomitant use of CYP3A4 inhibitors and venlafaxine may increase levels of venlafaxine and ODV. Therefore, caution is advised if a patient's therapy includes a CYP3A4 inhibitor and venlafaxine concomitantly.
Metoprolol
Concomitant administration of venlafaxine increase plasma concentrations of metoprolol without altering the plasma concentrations of its active metabolite, α-hydroxymetoprolol. Venlafaxine reduce the blood pressure lowering effect of metoprolol. The clinical relevance of this finding is unknown. Metoprolol did not alter the pharmacokinetic profile of venlafaxine or its active metabolite, O- Desmethyl venlafaxine. Caution should be exercised with co- administration of venlafaxine and metoprolol.
Risperidone
No clinically relevant pharmacokinetic interaction appears to occur between risperidone and venlafaxine.
Diazepam
Diazepam does not appear to affect the pharmacokinetics of either venlafaxine or O-Desmethyl venlafaxine. Venlafaxine has no effects on the pharmacokinetics and pharmacodynamics of diazepam and its active metabolite, desmethyldiazepam.
Lithium
Symptoms similar to those of the serotonin syndrome have developed in a few patients taking lithium with venlafaxine. No clinically significant pharmacokinetic interaction appears to occur between these two drugs.
Drugs Highly Bound to Plasma Proteins
Venlafaxine is not highly bound to plasma proteins; therefore, administration of venlafaxine to a patient taking another drug that is highly protein bound is not expected to cause increased free concentrations of the other drug.
Drugs Metabolized by Cytochrome P450 Isoenzymes
Venlafaxine is a relatively weak inhibitor of CYP2D6. Venlafaxine did not inhibit CYP3A4, CYP1A4, and CYP2C9.
STATEMENT ON USAGE DURING PREGNANCY AND LACTATION
The safety of venlafaxine in human pregnancy has not been established. Venlafaxine must be administered to pregnant women only if the expected benefits outweigh any possible risk. If venlafaxine is used until or shortly before birth, discontinuation effects in the newborn should be considered. Neonates exposed to Venlafaxine late in the third trimester have developed complications requiring respiratory support or prolonged hospitalization. Such complications can arise immediately upon delivery.
Venlafaxine and O-Desmethyl venlafaxine are excreted in human milk; therefore, a decision should be made whether not to breast-feed or to discontinue venlafaxine.
Observational data indicate an increased risk (less than 2-fold) of postpartum haemorrhage following SSRI/SNRI exposure within the month prior to birth.
ADVERSE EFFECTS / UNDESIRABLE EFFECTS
Body as a Whole
Common: Asthenia/fatigue
Uncommon: Photosensitivity reaction Very Rare: Anaphylaxis
Cardiovascular
Common: Hypertension, Vasodilatation (mostly hot flashes/flushes)
Uncommon: Hypotension, Postural hypotension, Syncope, Tachycardia
Very Rare: QT prolongation. Ventricular fibrillation, Ventricular tachycardia (including torsade de pointes)
Digestive
Common: Appetite decreased, Constipation, Nausea, Vomiting
Uncommon: Bruxism, diarrhea Very Rare: Pancreatitis
Hematological/Lymphatic
Uncommon: Ecchymosis, Mucous membrane bleeding
Rare: Prolonged bleeding time, Thrombocytopenia
Very Rare:Blood dyscrasias (including agranulocytosis, aplastic anemia, neutropenia and pancytopenia)
Metabolic/Nutritional
Common: Serum cholesterol increased (particularly with prolonged administration and possibly with higher doses), Weight loss
Uncommon: Abnormal liver function tests, Hyponatremia, Weight gain
Rare: Hepatitis, Syndrome of Inappropriate Antidiuretic Hormone Secretion (SIADH)
Very Rare: Prolactin increased
Musculoskeletal
Very Rare: Rhabdomyolysis
Nervous
Common: Abnormal dreams, Decreased libido, Dizziness, Dry mouth, increased muscle tonus, Insomnia, Nervousness, Paresthesia, Sedation, Tremor Uncommon: Apathy, Hallucinations, Myoclonus, Agitation
Rare: Akathisia, Convulsion, Manic Reaction, Neuroleptic Malignant
Very Rare : Delirium, extra pyramidal reactions (including dystonia, and dyskinesia), tardive dyskinesia
Respiratory
Common: Yawning
Very Rare: Pulmonary eosinophilia
Skin
Common: Sweating (Including Night Sweats)
Uncommon: Rash, Alopecia
Very Rare: Erythema multiforme, Stevens - Johnson syndrome, pruritus, urticaria
Special Senses
Common: Abnormality of accommodation, mydriasis. Visual disturbance
Uncommon: Altered taste sensation, Tinnitus
Very Rare: Angle closure glaucoma
Urogenital
Common: Abnormal ejaculation/orgasm (males), Anorgasmia, Erectile dysfunction, Urination impaired (mostly hesitancy)
Uncommon: Abnormal orgasm (females), Menorrhagia, Urinary retention
The following symptoms have been reported in association with abrupt discontinuation or dose- reduction, or tapering of treatment; hypomania, anxiety, agitation, nervousness, confusion, insomnia or other sleep disturbances, fatigue, somnolence, paresthesia, dizziness, convulsion, Vertigo, headache, tinnitus, sweating, dry mouth, anorexia, diarrhea, nausea and vomiting. The majority of discontinuation reactions are mild and resolve without treatment.
Pediatric Patients
In general, the adverse reaction profile of venlafaxine in children and adolescents (ages 6 to 17) was similar to that seen for adults. As with adults, decreased appetite, weight loss, increased blood pressure, and increased serum cholesterol were observed. There were increased reports of hostility and, especially in Major Depressive Disorder, suicide-related adverse events such as suicidal ideation and self-harm.
Additionally, the following adverse reactions were observed in pediatric patients; abdominal pain, agitation, dyspepsia, ecchymosis, epistaxis, and myalgia.
OVERDOSE AND TREATMENT
In post marketing experience, overdose with venlafaxine was reported predominantly in combination with alcohol and/or other drugs. The most commonly reported events in overdose include tachycardia, changes in level of consciousness (ranging from somnolence to coma), mydriasis, convulsion, and vomiting. Electrocardiographic changes (e.g. prolongation of QT interval, bundle branch block, QRS prolongation), ventricular tachycardia, bradycardia, hypotension, vertigo, and death have been reported.
General supportive and symptomatic measures are recommended: cardiac rhythm and vital signs must be monitored.
When there is a risk of aspiration, induction of emesis is not recommended.
Gastric lavage may be indicated if performed soon after ingestion or in symptomatic patients. Administration of activated charcoal may also limit drug absorption.
Forced diuresis, dialysis, hemoperfusion and exchange transfusion are unlikely to be of benefit. No specific antidotes for venlafaxine are known.
STORAGE CONDITIONS
Store below 30°C. Protect from light and moisture.
PACKAGING AVAILABLE
VENLIFT ER 37.5 mg, 75 mg and 150 mg capsules are packed in Alu-Alu blister of 10 capsules.
Such blister containing 10 capsules are packed into carton of 10's, 30's and 100's. Not all presentations or all pack sizes may be marketed.
DATE OF REVISION OF PACKAGE INSERT
31st March 2022

torrent PHARMA

Manufactured by :
TORRENT PHARMACEUTICALS LTD.
Indrad-382 721, Dist. Mehsana, INDIA.