Safety Data Sheet
VENLAFAXINE HYDROCHLORIDE TABLETS

Strength: 25/37.5/50/75 and 100 mg **Pack Size:** 30,60,90,100,500,1000 Tablets per bottle **Revision No.:** 02

EMERGENCY OVERVIEW

Each Venlafaxine Hydrochloride tablets intended for oral administration contains Venlafaxine Hydrochloride and excipients generally considered to be non- toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

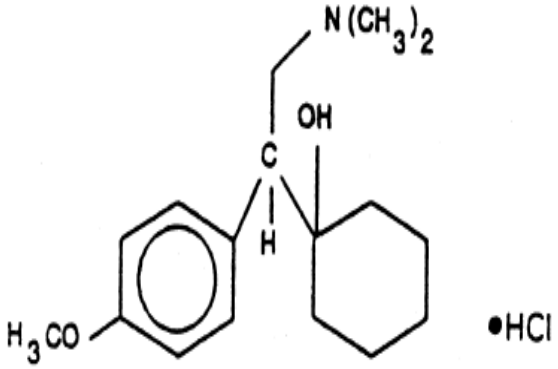
Section 1. Identification

Identification of the product

Product name: **Venlafaxine Hydrochloride Tablets**

Chemical Formula: $C_{17}H_{27}NO_2$ HCl

Chemical Name: (R/S)-1-[2-(dimethylamino)-1-(4-methoxyphenyl)ethyl] cyclohexanol hydrochloride or (±)-1-[α-[(dimethyl-amino)methyl]-p-methoxybenzyl] cyclohexanol hydrochloride.



Manufacturer / supplier identification

Company: **Cadila Healthcare Ltd. Ahmedabad, India**

Address: Sarkhej – Bavla. N.H. 8A, Moraiya. Tal. Sanand. Dist. Ahmedabad – 382210. State: Gujarat. India

Contact for information: Tel.: +91 79 6868100 Fax: +91 79 3750319

Emergency Telephone No. Tel.: +91 79 6868100

Recommended use / Therapeutic Category Antidepressant

Restriction on Use / Contraindications:	Hypersensitivity to venlafaxine hydrochloride or to any excipients in the formulation. Concomitant use in patients taking monoamine oxidase inhibitors (MAOIs) is contraindicated.

Section 2. Hazard(s) Information

Dose and Administration

The recommended starting dose for venlafaxine hydrochloride tablets is 75 mg/day, administered in two or three divided doses, taken with food. Depending on tolerability and the need for further clinical effect, the dose may be increased to 150 mg/day. If needed, the dose should be further increased up to 225 mg/day.

Adverse Effects

Body System	Preferred Term
Body as a Whole	Headache,Asthenia,Infection, Chills, Chest pain, Trauma.
Cardiovascular	Vasodilatation,Increased blood pressure/ hypertension, Tachycardia, Postural hypotension.
Dermatological	Sweating, Rash, Pruritus
Gastrointestinal	Nausea, Constipation, Anorexia, Diarrhea, Vomiting Dyspepsia, Flatulence
Metabolic	Weight loss
Nervous System	Somnolence, Dry mouth, Dizziness, Insomnia,Nervousness,Anxiety, Tremor,Abnormal dreams, Hypertonia, Paresthesia Libido decreased, Agitation, Confusion, Thinking abnormal Depersonalization, Depression, Urinary retention, Twitching
Urogenital System	Abnormal ejaculationm, Orgasmm, Impotence, Urinary frequency, Urination impaired, Orgasm disturbance.

Over Dose Effect

In postmarketing experience, overdose with venlafaxine has occurred predominantly in combination with alcohol and/or other drugs. The most commonly reported events in overdosage include tachycardia, changes in level of consciousness (ranging from somnolence to coma), mydriasis, seizures, and vomiting.

	Electrocardiogram changes (e.g., prolongation of QT interval, bundle branch block, QRS prolongation), ventricular tachycardia, bradycardia, hypotension, rhabdomyolysis, vertigo, liver necrosis, serotonin syndrome, and death have been reported.
Medical Conditions	All patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases.
Contraindications	Hypersensitivity to venlafaxine hydrochloride or to any excipients in the formulation. Concomitant use in patients taking monoamine oxidase inhibitors (MAOIs) is contraindicated
Pregnancy Category	Venlafaxine did not cause malformations in offspring of rats or rabbits given doses up to 11 times (rat) or 12 times (rabbit) the maximum recommended human daily dose on a mg/kg basis, or 2.5 times (rat) and 4 times (rabbit) the human daily dose on a mg/m2 basis.
Pregnancy Category	C

Section 3. Composition / information on ingredient

Component	**Exposure Limit**	**CAS No.**
Principle Component :		
Venlafaxine HCl	Not Found	99300-78-4
Inactive Ingredients :		
Lactose monohydrate	Not Found	10039-26-6
Magnesium stearate	Not Found	557-04-0
Microcrystalline cellulose	Not Found	9004-34-6
Sodium starch glycolate	Not Found	9063-38-01
Ferric oxide red	Not Found	1309-37-01
Ferric oxide yellow	Not Found	1309-37-01

Section 4. First - aid measures

General	Remove from exposure. Remove contaminated Clothing. Person developing serious hypersensitivity reaction must receive medical attention.

Overdose Treatment	Ensure an adequate airway, oxygenation, and ventilation. Monitor cardiac rhythm and vital signs. Induction of emesis is not recommended. Gastric lavage with a large-bore orogastric tube with appropriate airway protection, if needed, may be indicated if performed soon after ingestion or in symptomatic patients. Activated charcoal should be administered. Due to the large volume of distribution of this drug, forced diuresis, dialysis, hemoperfusion and exchange transfusion are unlikely to be of benefit. No specific antidotes for venlafaxine are known.

Section 5. Fire - fighting measures

Flash point	Not Found	**Upper Flammable Limit:**	Not Found
Auto-Ignition Temperature:	Not Found	**Lower Flammable Limit:**	Not Found
Extinguishing Media	Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.	**Fire and Explosion Hazard**	This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with the dry material to dissipate the potential build-up of static electricity.

Fire Fighting Procedure	As with all fires, evacuate personnel to a safe area. Fire fighter should use self- contained breathing equipment and protective clothing.

Section 6. Accidental Release Measures

Spill Response	Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.

Section 7. Handling and Storage

Storage	Store at 20° to 25°C (68° to 77°F) in a dry place**.** Dispense in a well closed container as defined in the USP.
Incompatibilities:	No Data available.

Section 8. Exposure controls / personal protection

Respiratory Protection	Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to generate, use of suitable dust mask would be appropriate.

Skin Protection	Skin protection is not normally necessary, however it is good practice to avoid contact with chemical to use suitable gloves when handling.
Eye protection	Eye protection is not normally necessary. If concerned wear protective goggles or glasses. Wash hands prior to touching eye and in particular handling contact lenses.
Protective Clothing	Protective clothing is not normally necessary, however it is good practice to use apron.
Engineering Control	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Section 9. Physical and chemical properties

Appearance

Venlafaxine Hydrochloride Tablets equivalent to 25 mg of venlafaxine are peach-colored, round, flat, beveled-edged tablets with bisect on one side; one side of bisect is debossed with logo of "ZC" and other side is debossed with "64" and other plain.

Venlafaxine Hydrochloride Tablets equivalent to 37.5 mg of venlafaxine are peach- colored, round, flat, beveled-edged tablets with bisect on one side; one side of bisect is debossed with logo of "ZC" and other side is debossed with "65" and other plain.

Venlafaxine Hydrochloride Tablets equivalent to 50 mg of venlafaxine are peach-colored, round, flat, beveled-edged tablets with bisect on one side; one side of bisect is debossed with logo of "ZC" and other side is debossed with "66" and other plain .

Venlafaxine Hydrochloride Tablets equivalent to 75 mg of venlafaxine are peach-colored, round, flat, beveled-edged tablets with bisect on one side; one side of bisect is debossed with logo of "ZC" and other side is debossed with "67" and other plain.

Venlafaxine Hydrochloride Tablets equivalent to 100 mg of venlafaxine are peach- colored, round, flat, beveled-edged tablets with bisect on one side; one side of bisect is debossed with logo of "ZC" and other side is debossed with "68" and other plain.

Solubility in water	No Data Available	**Odour**	Odourless
Boiling point	No Data Available	**Melting Point**	No Data Available
Evaporation rate	No Data Available	**Vapour density**	No Data Available
Reactivity in water	No Data Available	**Evaporation rate**	No Data Available
% Volatile by volume	No Data Available	**Specific gravity**	No Data Available
		Vapour pressure	No Data Available

Other information	Venlafaxine hydrochloride is a white to off-white crystalline powder; soluble in methanol and in water. Its octanol: water (0.2 M sodium chloride) partition coefficient is 0.43.

Section 10. Stability and Reactivity

Condition to avoid	Avoid exposure to extreme heat, light and moisture.	**Stable**	Stable under normal ambient and anticipated storage and handling conditions.
Decomposition Products	No Data Available	**Hazardous Reaction**	No data available.
Incompatibilities:	No Data available		

Section 11. Toxicological information

General	Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation.
Target organ	Eye contact, Skin contact and inhalation is not great risk as this product is tablet.
Other	Not applicable

Section 12. Ecological information

Do not allow product to enter drinking water supplies, waste water or soil

Section 13. Disposal Consideration

Dispose the waste in accordance with all applicable Federal, State and local laws.

Section 14. Transport Information

The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG).

Section 15. Regulatory Information

Generic Medicine. Approved by USFDA & the ANDA Number is 077653

Section 16. Other information

None

Date of issue: 28/05/2015 **Supersedes edition of:** 01