Material Safety Data Sheet
Venlafaxine Extended-Release Capsules

Strength: 37.5 mg, 75 mg and 150 mg **Pack Size:** 30/90/100/500/1000 capsules per bottle **Revision No.:** 00

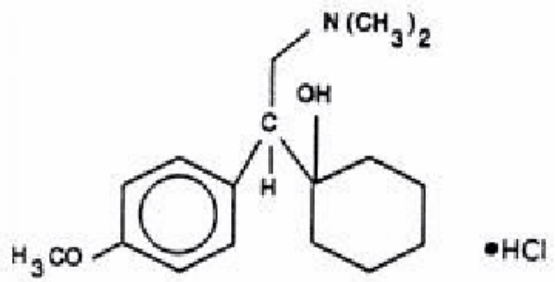
EMERGENCY OVERVIEW

Venlafaxine hydrochloride extended-release capsule for oral administration that 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 of the substance

Identification of the product

Product name:	Venlafaxine Hydrochloride Extended-release Capsules
Formula:	$C_{17}H_{27}NO_2$ HCl
Chemical Name:	(R/S)-1-[2-(dimethylamino)-1-(4-methoxyphenyl)ethyl] cyclohexanol hydrochloride or (±)-1-[α-[(dimethylamino)methyl]-p-methoxybenzyl] cyclohexanol hydrochloride
Therapeutic Category	Antidepressant



venlafaxine hydrochloride

Manufacturer / supplier identification

Company:		**Cadila Healthcare Ltd. Ahmedabad, India**
Contact for information:	Tel.:	+91 79 6868100 Fax: +91 79 3750319
Emergency telephone No.		Tel.: +91 79 6868100

Section 2. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component :		
venlafaxine	Not Found	99300-78-4
Inactive Ingredients :		
colloidal anhydrous silica	Not Found	7631-86-9
cetostearyl alcohol	Not Found	36653-82-4
gelatin	Not Found	NA
hypromellose	Not Found	9004-65-3
microcrystalline cellulose	Not Found	9004-34-6
polyacrylate dispersion	Not Found	NA
sodium lauryl sulfate	Not Found	151-21-3
talc	Not Found	14807-96-6
titanium dioxide	Not Found	13463-67-7

Section 3. Health Hazards Information

Dose and Administration

Labor and Delivery:
The effect of venlafaxine on labor and delivery in humans is unknown

Nursing Mothers:
Venlafaxine and ODV have been reported to be excreted in human milk. Because of the potential for serious adverse reactions in nursing infants from venlafaxine hydrochloride extended-release capsules, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use:
Safety and effectiveness in the pediatric population have not been established

Adverse Effects

Asthenia, Vasodilatation, Hypertension,Nausea ,Constipation ,Anorexia Vomiting,Flatulence,Weight Loss,Dizziness,Somnolence,Insomnia,Dry Mouth,Nervousness,Abnormal Dreams,Tremor,Depression Paresthesia Libido,Decreased,Agitation,Pharyngitis, Yawn,Sweating,Abnormal Vision,Abnormal Ejaculation (male) , Impotence Anorgasmia (female)

Over Dose Effect

changes in level of consciousness tachycardia, mydriasis, seizures, and vomiting ventricular tachycardia, bradycardia, hypotension, rhabdomyolysis, vertigo, liver necrosis, serotonin syndrome, and death have been reported.

Medical Conditions	Thoughts about suicide or dying Attempts to commit suicide New or worse depression New or worse anxiety Feeling very agitated or restless Panic attacks Trouble sleeping (insomnia) New or worse irritability Acting aggressive, being angry, or violent Acting on dangerous impulses An extreme increase in activity and talking (mania) Other unusual changes in behavior or mood
Contraindications	Hypersensitivity to venlafaxine hydrochloride or to any excipients in the formulation Concomitant use in patients taking monoamine oxidase inhibitors (MAOIs) is contraindicated
Pregnancy Comments	Patients should be advised to notify their physician if they become pregnant or intend to become pregnant during therapy. *Nursing:*Patients should be advised to notify their physician if they are breast-feeding an infant.
Pregnancy Category	***C***

Section 4. First aid measures

General

Inhalation

Remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.

contact with skin

Immediately wash skin with soap and copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention.

contact with eyes
Immediately flush eyes with copious amounts of water for at least 15 minutes. Seek medical advice

Ingestion
If swallowed, wash out mouth with water, provided person is concious. Seek medical advice

Remove and wash/dispose of contaminated clothing promptly.

Overdose Treatment	Ensure an adequate airway, oxygenation, and ventilation. Monitor cardiac rhythm and vital signs. General supportive and symptomatic measures are also recommended. 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)

Section 8. Exposure controls and 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.

Section 9. Physical and chemical properties

Appearance

Venlafaxine Hydrochloride Extended-release Capsules, 37.5 mg are white to off-white free flowing pellets filled in size '3' hard gelatin capsules with grey colored cap printed with "ZA-35" in black ink & white body printed with "37.5 mg" in black ink

Venlafaxine Hydrochloride Extended-release Capsules, 75 mg are white to off-white free flowing pellets filled in size '1' hard gelatin capsules with peach colored cap printed with "ZA-36" in black ink & white body printed with "75 mg" in black ink

Venlafaxine Hydrochloride Extended-release Capsules, 150 mg are white to off-white free flowing pellets filled in size '0' hard gelatin capsules with dark orange colored cap printed with "ZA-37" in black ink & white body printed with "150 mg" in black ink

Solubility in water	Soluble in water (572 mg/ml)	**Odour**	Odourless
Boiling point	No Data Available	**Melting Point**	215-217
Evaporation rate	No Data Available	**Vapour density**	No Data Available
Reactivity in water	No Data Available	**Evaporation rate**	No Data Available
Percentage Volatile by volume	No Data Available	**Specific gravity**	No Data Available
Vapour pressure	No Data Available		
Other information	Not Applicable		

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

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

Section 14. Transport Information

May be shipped normally as a non hazardous material.

Section 15. Regulatory Information

Generic Medicine. Approved by USFDA & the ANDA Number is. 090174

Section 16. Other information

None

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The information contained herein is based on the state of our knowledge. It Characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.