



HETERO LABS LIMITED

"Hetero Corporate", 7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad - 500 018. A.P., INDIA.
Tel : 91-40-23704923/24/25, Fax : 91-40-23704926, 23714250
e-mail : contact@heterodrugs.com URL : http://www.heterodrugs.com

SAFETY DATA SHEET

Section 1: Identification

Material	Venlafaxine Hydrochloride Extended-Release Capsules USP, 37.5mg, 75mg and 150mg
Other means of identification Synonyms	Venlafaxine Hydrochloride Extended-Release Capsules
Recommended use	Pharmaceutical product
Classification	Antidepressant
Manufacturer	Annora Pharma Private Limited , Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India (IND)
Distributor	Camber Pharmaceuticals, Inc., Piscatway, NJ 08854

Section 2: Hazard(s) Identification

Emergency Overview

This contains an active pharmaceutical ingredient that can affect body functions; handle with caution.

Appearance	Capsule
Physical State	Solid
odor	Not applicable
Therapeutic Target Organ(s)	Central nervous system.
Potential Environmental Effects	See Section 12

Section 3: Composition/Information on Ingredients

Ingredients	CAS
Venlafaxine Hydrochloride	99300-78-4

Section 4: First-Aid Measures

Eye Contact	In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Skin Contact	Take off contaminated clothing and shoes immediately. Wash off with soap and plenty of water. If skin irritation persists, call a physician.
Ingestion	Immediate medical attention is required
Inhalation	Move to fresh air. Artificial respiration and/or oxygen may be necessary. If symptoms persist, call a physician.

Section 5: Fire-Fighting Measures

Flammable Properties	Not flammable
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Extinguishing Media:

Suitable Extinguishing Media

Use water spray, foam, dry chemical or carbon dioxide.

Unsuitable Extinguishing Media

Do not use water jet.

Fire Fighting

Evacuate area and fight fire from a safe distance. Cool closed containers exposed to fire with water spray. In the event of fire and/or explosion do not breathe fumes.

Hazardous Combustion Products

Carbon oxides, nitrogen oxides.

Protective Equipment and Precautions for Firefighters

In the event of fire, wear self-contained breathing apparatus and special protective equipment for fire fighters.

Section 6: Accidental Release Measures

Personal Precautions

Safety glasses or goggles when splash potential exists

Environmental precautions

Prevent product from entering drains. Local authorities should be advised if a significant spill cannot be contained.

Methods for Cleaning up

Take up mechanically and collect in suitable container for disposal. Clean contaminated surface thoroughly. Avoid formation of dust and aerosols.

Section 7: Handling and Storage

Handling

For prolonged or repeated skin contact use suitable protective gloves. The selection of gloves for a specific activity must be based on the material's properties and on possible permeation and degradation that may occur under the circumstances of use. Care must be exercised if insufficient data are available and further guidance should be sought from your local EHS department. Potential allergic reactions can occur with certain glove materials (e.g. Latex) and therefore these should be avoided. Glove selection must take into account any solvents and other hazards present.

Storage

Store at 20° to 25°C (68° to 77°F)
[see USP Controlled Room Temperature].



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Section 8: Exposure Controls/Personal Protection

Emergency Limits

Venlafaxine Hydrochloride

Not Available

Personal Protective Equipment:

Eye/face Protection

If contact is likely, safety glasses with side shields are recommended

Skin Protection

Wear suitable protective clothing

Respiratory Protection

When workers are facing concentrations above the exposure limit they must use appropriate certified respirators

General Hygiene Considerations

When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands before breaks and at the end of workday. Limit access to only personnel trained in the safe handling of this material. Consult a health and safety professional for specific PPE, respirator, and risk assessment guidance.

Other

Section 9: Physical and Chemical Properties

Appearance

Capsule

Color

As per Description

Physical State

Solid

Venlafaxine Hydrochloride Extended-Release Capsules USP, 37.5 mg

White to off-white colored, round to oval shaped pellets filled in size 3 hard Gelatin capsules with grey opaque cap imprinted with 'V' in black color, white opaque body imprinted with '9' in black color.

Bottle of 30 Tablets (NDC 31722-002-30)

Bottle of 90 Tablets (NDC 31722-002-90)

Bottle of 500 Tablets (NDC 31722-002-05)

Blister Package (10×10) (NDC 31722-002-01)

Description

Venlafaxine Hydrochloride Extended-Release Capsules USP, 75 mg

White to off white colored, round to oval shaped pellets filled in size 1 hard Gelatin capsules with peach opaque cap imprinted with 'V' in black color, white opaque body imprinted with '10' in black color.

Bottle of 30 Tablets (NDC 31722-003-30)

Bottle of 90 Tablets (NDC 31722-003-90)

Bottle of 500 Tablets (NDC 31722-003-05)

Blister Package (10×10) (NDC 31722-003-01)



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Venlafaxine Hydrochloride Extended-Release Capsules USP, 150 mg

White to off white colored, round to oval shaped pellets filled in size '0' hard Gelatin capsules with orange opaque cap imprinted with 'V' in black color, white opaque body imprinted with '11' in black color.

Bottle of 30 Tablets (NDC 31722-004-30)

Bottle of 90 Tablets (NDC 31722-004-90)

Bottle of 500 Tablets (NDC 31722-004-05)

Blister Package (10×10) (NDC 31722-004-01)

Section 10: Stability and Reactivity

Chemical stability	Stable at room temperature.
Conditions to Avoid	No data available
Materials to Avoid	No materials to be especially mentioned.
Hazardous Decomposition Products	None under normal use.
Possibility of Hazardous Reactions	None under normal use.

Section 11: Toxicological Information

The following effects are based on the Active Pharmaceutical Ingredient.

Acute Toxicity - Venlafaxine Hydrochloride

Inhaled

The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified by EC Directives using animal models). Nevertheless, adverse systemic effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.

If prior damage to the circulatory or nervous systems has occurred or if kidney damage has been sustained, proper screenings should be conducted on individuals who may be exposed to further risk if handling and use of the material result in excessive exposures.



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Skin Contact

Skin contact is not thought to have harmful health effects (as classified under EC Directives); the material may still produce health damage following entry through wounds, lesions or abrasions.

Limited evidence exists, or practical experience predicts, that the material either produces inflammation of the skin in a substantial number of individuals following direct contact, and/or produces significant inflammation when applied to the healthy intact skin of animals, for up to four hours, such inflammation being present twenty-four hours or more after the end of the exposure period. Skin irritation may also be present after prolonged or repeated exposure; this may result in a form of contact dermatitis (nonallergic). The dermatitis is often characterised by skin redness (erythema) and swelling (oedema) which may progress to blistering (Vesiculation), scaling and thickening of the epidermis. At the microscopic level there may be intercellular oedema of the spongy layer of the skin (spongiosis) and intracellular oedema of the epidermis.

Photosensitiser: Certain individuals working with this substance may show an abnormally heightened or allergic reaction of the skin to the influence of sunlight. This results in sensitivity to sun, which may be severe, unless protective covering and 15+SPF sunblock cream are used. Responses may vary from sunburn-like responses to edematous, vesiculated lesions or bullae.

Open cuts, abraded or irritated skin should not be exposed to this material

Entry into the blood-stream through, for example, cuts, abrasions, puncture wounds or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.



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Eye	Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may cause transient discomfort characterised by tearing or conjunctival redness (as with windburn). Slight abrasive damage may also result. The material may produce foreign body irritation in certain individuals.
Multiple Dose Toxicity - Venlafaxine Hydrochloride	
No Toxicologic Effect Dose/Species/Study Length	See Carcinogenicity
Maximum Tolerated Dose (MTD), Oral - Venlafaxine Hydrochloride	
Carcinogenicity	Studies in rats and mice for 24 and 18 months, respectively, have revealed no evidence of an increased risk of tumor development.
Genetic Toxicity	No evidence of mutagenicity was observed in a battery of in vitro and in vivo assays. There was a clastogenic response in the in vivo chromosomal aberration assay in rat bone marrow.
Reproductive Toxicity	Studies in rats were found to have no effect on fertility and reproductive performance.
Developmental Toxicity	No teratogenic effects were observed in rats or rabbits. A decrease in pup weight, an increase in still born pups, and an increase in pup deaths during the first 5 days of lactation have also been reported when rats were dosed at pregnancy and continued until weaning.
12. ECOLOGICAL INFORMATION	
Chemical Fate Information - Venlafaxine Hydrochloride	
Mobility	Freely soluble in Methanol and Water, soluble in anhydrous Ethanol and slightly soluble or practically insoluble in Acetone..
Biodegradability	Not inherently biodegradable.
Stability in Water	Relatively stable.
Bioaccumulation	Bioaccumulation is unlikely.
Ecotoxicity - Venlafaxine Hydrochloride	
Do NOT allow product to come in contact with surface waters or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash-waters. Wastes resulting from use of the product must be disposed of on site or at approved waste sites.	



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13. DISPOSAL CONSIDERATIONS

Waste Disposal Method

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

Transport Information

This material is not regulated for transportation as a hazardous material/dangerous goods.

15. REGULATORY INFORMATION

According to present data no classification and labeling is required according to Directives 67/548/EEC or 1999/45/EC.

16. OTHER INFORMATION

Issue Date : 12-10-2018

Version : 00

Further information

Revision date: New issue

Revision note: New issue

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose. Annora Pharma Private Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Annora Pharma Private Limited reserves the right to revise this SDS.