



# SAFETY DATA SHEET

## Venlafaxine Extended Release Tablets

### 1. IDENTIFICATION

**Manufacturer:**

Ascent Pharmaceuticals Inc  
400 S. Technology Drive  
Central Islip, NY 11722  
USP

**Emergency Phone:**

1-855-221-1622

**Common Name:** Venlafaxine Extended Release Tablets

**Synonym(s):** Not Applicable

**Trade Name(s):** Venlafaxine Extended Release Tablets, 37.5 mg, 75 mg, 150 mg and 225 mg.

### 2. HAZARDS IDENTIFICATION

Not considered hazardous when handled under normal conditions. Accidental ingestion of large amounts may be harmful.

### EMERGENCY OVERVIEW

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

**Routes of Entry:** Ingestion

**Appearance:** Tablet

**Physical State:** Solid

**Odor:** Not Applicable

**Therapeutic Target Organs:** Central nervous system

### 3.COMPOSITION / INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>CAS</u>	<u>Concentration*</u>
		<b>37.5 mg, 75 mg, 150 mg and 225 mg</b>
Venlafaxine Hydrochloride	99300-78-4	≈ 40 % to 44 %
Excipients	NA	≈ 56-60 %

\* All Concentrations are percent by weight.

### 4. FIRST AID MEASURES

**Inhalation:** If breathing is difficult, move to fresh air, if not breathing give artificial respiration. Get medical attention immediately.

**Skin Contact:** Wash with soap and water for at least 15 minutes. Get medical attention if symptoms occur.

**Eye Contact:** Any material that contacts the eye should be washed out immediately with water for at least 15 minutes. If easy to do, remove contact lenses if worn. Get medical attention if symptoms persist.

**Ingestion:** Call a physician or poison control center immediately. Never give anything by mouth to a victim who is unconscious or is having convulsions. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.



## 5. FIRE-FIGHTING MEASURES

**Extinguishing Media:** Use water spray, dry chemical, carbon dioxide or material appropriate for fire in surrounding area

**Unusual Fire & Explosion Hazards:** Not Applicable.

**Special Fire Fighting Procedures:** Wear full protective clothing and self-contained breathing apparatus.

**Protective Measures:** Prevent runoff from fire control or dilution from entering streams, sewers, or drinking water supply.

## 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions:** Use personal protective equipment. Immediately contact emergency personnel. Keep unnecessary personnel away. Follow all firefighting procedures.

**Environmental precautions:** Do not release in to the environment.

**Spill Cleanup methods:** Sweep up or vacuum up spillage and collect in suitable container for disposal. Should not be released into the environment. Do not flush to sewer.

## 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:** This material must be stored at 20° to 25° C (68° to 77° F). See USP Controlled room temperature. Store the medicine in a tight, light resistant container at room temperature, away from heat, moisture, and direct light.



## 8.EXPOSURE CONTROLS / PERSONAL PROTECTION

Compressed tablets are not considered hazardous under normal handling procedures and protective equipment is not required. The following are recommended for manufacturing or other situations where exposure to the powder may occur.

**Protective Measures:** Not required when handling tablets or containers. Ventilation should be matched to conditions.

**Respiratory Protection:** Not required when handling tablets or containers. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary. Ventilation should be matched to conditions.

**Hand Protection:** Chemical resistant gloves.

**Eye Protection:** Wear safety glasses with side shields (or goggles). If the work environment or activity involves dusty conditions, mist or aerosols, wear the appropriate goggles. Wear a face shield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Skin and Body Protection:** Not required when handling tablets. If containers are compromised or exposure is likely --wear: Goggles, Lab Coat and Gloves

**Hygiene Measures:** Wash skin thoroughly with soap and water.

## 9.PHYSICAL AND CHEMICAL PROPERTIES

**Physical Properties:**

**Physical State:** Solid

**Form:** Tablets

**Appearance:**

**Venlafaxine Hydrochloride Extended-Release Tablets USP, 37.5 mg:** White to off White, Film Coated, round biconvex tablets printed with "392" in Black Ink

**Venlafaxine Hydrochloride Extended-Release Tablets USP, 75 mg:** White to off White, Film Coated, round biconvex tablets printed with "393" in Black Ink



**Venlafaxine Hydrochloride Extended-Release Tablets USP, 150 mg:** White to off White, Film Coated, round biconvex tablets printed with “394” in Black Ink

**Venlafaxine Hydrochloride Extended-Release Tablets USP, 225 mg:** White to off White, Film Coated, round biconvex tablets printed with “395” in Black Ink

## 10. STABILITY AND REACTIVITY

**Possibility of hazardous reactions:** Stable under ordinary conditions of use and storage.

**Conditions to avoid:** Excessive heat & Moisture.

**Incompatible materials:** No materials to be especially mentioned..

**Hazardous Decomposition products:** None under normal use.

## 11. TOXICOLOGICAL INFORMATION

**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.

**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 characterized by skin redness (erythema) and swelling (oedema) which may progress to blisterin (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. Photosensitizer: 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.

**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 characterized by tearing or conjunctival redness (as with windburn). Slight abrasive damage may also result. The material may produce foreign body irritation in certain individuals.

## 12. ECOLOGICAL INFORMATION

**General information:** The information presented below pertains to the individual ingredients, and not to the mixture(s) or final formulations.

**Ecotoxicity:** No data available.

**Acute toxicity (Aquatic invertebrates):** No data available.

**Bioaccumulation:** No data available.

**Mobility:** Freely soluble in Methanol and Water, soluble in anhydrous Ethanol and slightly soluble or practically insoluble in Acetone.

## 13. DISPOSAL CONSIDERATIONS

**Waste Disposal:** 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

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



## 15. REGULATORY INFORMATION

Stated regulatory information chosen primarily for possible usage of Ascent Pharmaceutical, Inc. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

## 16. OTHER INFORMATION

SDS Sections Revised: New

### GLOSSARY:

SDS	Safety Data Sheet
NA	Not Applicable
CAS Number	Chemical Abstract Service Registry Number
NTP	National Toxicology Program
NIOSH	National Institute for Occupational Safety and Health
DOT	Department of Transportation
IMDG	International Maritime Dangerous Goods Code
ICAO	International Civil Aviation Organization
IATA	International Air Transport Association
IMO	International Maritime Organization
TSCA	Toxic Substances Control Act
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
SARA	Superfund Amendments and Reauthorization Act
OSHA	Occupational Safety and Health Administration

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