

EVISTA TABLETS

Version 1.3

Revision Date 01/10/2011

Print Date 10/09/2013

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : EVISTA TABLETS
Substance Number : 000004269883
Common Name : Raloxifene Hydrochloride Tablets

Chemical Name : Methanone, [6-hydroxy-2-(4-hydroxyphenyl)benzo[b]thien-3-yl][4-[2-(1-piperidinyl)ethoxy]phenyl]-, hydrochloride
Lilly Serial Number : 156758
LY Number : LY139481 Hydrochloride
Use of the Substance/Mixture : Pharmaceutical

Company : Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285

Telephone : 317-276-2000
Emergency telephone number : CHEMTREC: 1-800-424-9300 (Outside U.S. 1-703-527-3887)

Item Code : TA4166, VF0338, VF0316, TA4466, TA4165, TA4164, VF0317, VF0297, VF0298, TA4012, ND1002, TA4013, VF0374, SA1006, B02059, UC4165, ZD4165

SECTION 2. HAZARDS IDENTIFICATION**Emergency Overview****Lilly Lab Labeling Code****Health:** 2**Fire:** 1**Reactivity:** 0**Special:** Highly Potent, Reproductive Hazard,
Suspect Carcinogen**Special:**
P, R, sC**Primary Hazards:** Not hazardous if intact, Irritant (skin), Highly Potent, Reproductive, Suspect Carcinogen**Hazard Summary (Caution):** Not hazardous if intact. Effects of exposure to contents: May cause skin irritation. Highly Potent. This product may cause adverse reproductive effects. May cause cancer.**Emergency Overview**

Form : tablet
Colour : light yellow
Odour : odourless

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Potential Health Effects

- Skin : May irritate skin.
- Aggravated Medical Condition : None known.
- Primary Routes of Entry : Inhalation Skin contact
- Symptoms of Overexposure : Exposure to raloxifene hydrochloride resulted in skin rash/redness. Reproductive and/or developmental effects are associated with compounds in this pharmacological class.
- Additional Information : Capsules or tablets are intended for human consumption under guidance of a physician.

Carcinogenicity

- NTP No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
- IARC No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
- OSHA No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No.	Concentration [%]
Raloxifene Hydrochloride	82640-04-8	10 - 65
	NA	35 - 90

NA = Not applicable, Not assigned, or Not available.

SECTION 4. FIRST AID MEASURES

- Inhalation : Remove to fresh air. If breathing is irregular or stopped, administer artificial respiration. Call a physician immediately.
- Skin contact : Wash off immediately with plenty of water for at least 15 minutes. Take off all contaminated clothing immediately. Get medical attention if irritation develops and persists.
- Eye contact : In case of eye contact, remove contact lens and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Obtain medical attention.
- Ingestion : If conscious, give the victim plenty of water to drink. Never give anything by mouth to an unconscious person. Call a physician immediately.

Notes to physician

- Symptoms : Exposure to raloxifene hydrochloride resulted in skin rash/redness. Reproductive

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and/or developmental effects are associated with compounds in this pharmacological class.

SECTION 5. FIRE-FIGHTING MEASURES

Flash point	: not applicable	Upper explosion limit	: No data available
Autoignition temperature	: No data available	Flammability (solid, gas)	: No test data available.
Lower explosion limit	: No data available		
Suitable extinguishing media	: Water Carbon dioxide (CO2) Dry chemical		
Unusual Fire and Explosion Hazard.	: Dust may form explosive mixture in air. May release the following gases if heated to decomposition: Chloride.		
Special protective equipment for fire-fighters	: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.		

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions	: Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions).
Environmental precautions	: Try to prevent the material from entering drains or water courses. Refer to Sections 11 and 12 for health and environmental hazard information.
Methods for cleaning up	: Do not sweep. Preferred method for spill cleanup is by using a HEPA equipped vacuum. Be aware of potential for dust explosion when using electrical equipment. If vacuum is not available, lightly mist/wet material and remove by mopping or wet wiping.
Additional advice	: Refer to Sections 8, 11, 12 and 13 for more information.

SECTION 7. HANDLING AND STORAGE**Handling**

Advice on safe handling	: Avoid contact with skin, eyes and clothing. Wash hands thoroughly after handling. For personal protection see section 8.
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Storage

Requirements for storage areas and containers	: Keep container tightly closed in a dry and well-ventilated place.
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Relative vapour density : No data available Odor Threshold : No data available
 Evaporation rate : No data available

SECTION 10. STABILITY AND REACTIVITY

Conditions to avoid : None known.

Materials to avoid : Strong oxidizing agents

Hazardous decomposition products : May release the following gases if heated to decomposition: Chloride.

Thermal decomposition : Stable under normal conditions.

Hazardous reactions : Hazardous polymerisation does not occur.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute oral toxicity

- Raloxifene Hydrochloride: LD (rat) > 5,000 mg/kg
- Raloxifene: LD (Monkey) > 1,000 mg/kg

Acute inhalation toxicity

- Raloxifene: LC (Monkey) > 27 mg/m³ (8 h)

Acute dermal toxicity

- Raloxifene Hydrochloride: LD (rabbit) > 200 mg/kg

Skin irritation

- Raloxifene Hydrochloride: rabbit, slight irritation
Exposure to raloxifene hydrochloride resulted in skin rash/redness.

Eye irritation

- Raloxifene Hydrochloride: rabbit, slight irritation

Sensitisation

- Raloxifene Hydrochloride: Did not cause sensitization on laboratory animals.

Repeated dose toxicity

- Raloxifene Hydrochloride: Raloxifene hydrochloride is a Selective Estrogen Receptor Modulator (SERM) and is highly potent. Effects on reproductive organs have been reported in animal studies.

Carcinogenicity

- Raloxifene Hydrochloride: Increased incidences of ovarian, testicular, and prostatic tumors were reported in long-term studies in rodents. These effects were attributed to dose-dependent hormonal

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pharmacology.

Reproductive toxicity

- Raloxifene Hydrochloride: No pregnancies occurred when male and female rats were given daily doses of 5 mg/kg prior to and during mating. In female rats, disrupted estrous cycles and inhibited ovulation (all reversible), and delayed and disrupted embryo implantation resulting in prolonged gestation and reduced litter size were reported. Developmental effects reported included decreased fetal weight and delayed skeletal development, growth retardation, malformations of the heart, edema, and hydrocephaly in offspring. In male rats, daily doses up to 100 mg/kg for at least 2 weeks did not affect sperm production/quality or reproductive performance. Decreased prostate weights and a single case of aspermatogenesis were observed in dogs given 30 mg/kg for 6-months. No significant observations in sperm count/motility and morphology were observed in humans during a 3-month clinical trial when given daily doses of 120 mg.

Mutagenicity

- Raloxifene Hydrochloride: Result in genetic toxicity assays (in vitro and in vivo): Negative.

Further information

- Raloxifene Hydrochloride: Raloxifene hydrochloride is a Selective Estrogen Receptor Modulator (SERM) and is highly potent. Reproductive effects in females and developmental effects are associated with compounds in this pharmacological class, including raloxifene hydrochloride. Effects of exposure with therapeutic use in postmenopausal women not taking estrogen replacement therapy may include blood clots in veins, leg cramps, and hot flashes.

SECTION 12. ECOLOGICAL INFORMATION

Toxicity to fish

- Raloxifene Hydrochloride LC50 / 96 h / *Oncorhynchus mykiss* (rainbow trout): 1.45 mg/l
- Raloxifene No data available

Toxicity to algae

- Raloxifene Hydrochloride EC50 / *Selenastrum capricornutum*: 1.21 mg/l (average specific growth rate)

Effects on micro-organisms

- Raloxifene Hydrochloride IC50 / Fungus: > 1,000 mg/l
IC50 / mold: > 1,000 mg/l
IC50 / Bacteria (soil): > 1,000 mg/l
IC50 / Bacteria (n-fixing): > 1,000 mg/l
IC50 / blue-green algae: 875 mg/l

Toxicity to daphnia

- Raloxifene Hydrochloride EC50 / 48 h / *Daphnia magna* (Water flea) : 2.43 mg/l

Chronic Toxicity to daphnia

- Raloxifene Hydrochloride NOEC/ 23 d / *Daphnia magna* : 0.165 mg/l

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Lilly Aquatic Exposure Guideline

- Raloxifene Hydrochloride Acute Exposure of Aquatic Organisms: 0.01 µg/l
Chronic Exposure of Aquatic Organisms: 0.01 µg/l
Drinking Water: 3.5 µg/l

Biodegradability

- Raloxifene Hydrochloride Hydrolysis half-life (days): 1001, 410, 90 (pH 5, 7, 9)
Sewage sludge degradation half-life (0.47 g/L total suspended solids): 7.17 hours
Aerobic biodegradation half-life (0.03 g/L total suspended solids): 37 days

Bioaccumulation

- Raloxifene Hydrochloride log Kow: < 4.

SECTION 13. DISPOSAL CONSIDERATIONS

Waste disposal methods : In accordance with local and national regulations.

SECTION 14. TRANSPORT INFORMATION

IATA UN Number : 3077
Description of the goods : Environmentally hazardous substances, solid, n.o.s.
(Raloxifene Hydrochloride)
Class : 9
Packaging group : III
Labels : 9

IMDG UN Number : 3077
Description of the goods : Environmentally hazardous substances, solid, n.o.s.
(Raloxifene Hydrochloride)
Class : 9
Packaging group : III
Labels : 9
Marine pollutant : yes

Other information : Not dangerous goods in the meaning of DOT.

SECTION 15. REGULATORY INFORMATION

TSCA Status: Not On TSCA Inventory
82640-04-8 Raloxifene Hydrochloride



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DSL Status: This product contains the following components that are not on the Canadian DSL nor NDSL lists.
82640-04-8 Raloxifene Hydrochloride

California Prop. 65

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 313 Toxic Chemicals (40 CFR 372.65) - Supplier Notification Required

SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A)

SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SECTION 16. OTHER INFORMATION

Further information

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Eli Lilly and Company
Hazard Communication
317-651-9533