InvaGen Pharmaceuticals, Inc.

SAFETY DATA SHEET

Raloxifene Hydrochloride Tablets, USP

1. IDENTIFICATION

Manufacturer:

InvaGen Pharmaceuticals Inc
7, Oser Avenue
Hauppauge, NY 11788

Emergency Phone:

1-631-231-3233

Common Name: Raloxifene Hydrochloride Tablets

Chemical Family: Benzothiopene derivative, nonsteroidal

Synonym(s): Not Applicable

Chemical Name: Methanone, [6-hydroxy-2-(4-hydroxyphenyl) benzo[b]thien-3-yl]-[4-[2-(1-piperidinyl) ethoxy] phenyl]-, hydrochloride

Trade Name(s): Raloxifene Hydrochloride Tablets, USP 60 mg.

Therapeutic Category: Selective estrogen receptor modulator; Anti-estrogen

Molecular formula and weight: $C_{28}H_{27}NO_4.S.HCl$ **and Wt:** 510.04

2.HAZARDS IDENTIFICATION

Not considered hazardous when handled under normal conditions.

EMERGENCY OVERVIEW

Caution Statement: Intact Raloxifene Hydrochloride Tablets, USP are not considered to be a health hazard. Effects of exposure to contents may cause skin irritation, Highly Potent and Reproductive Hazard.

Routes of Entry: Oral

Effects of Overexposure: Tablets are intended for human consumption under guidance of a physician. Intact tablets are not considered hazardous under normal handling procedures.

Medical conditions Aggravated by Long Term Exposure: Hypersensitivity to material; active or past history of venous thromboembolic events, including deep vein thrombosis, pulmonary embolism, and retinal vein thrombosis; heart problems; neoplasms; impaired liver or kidney function; and undiagnosed uterine bleeding.

Carcinogenicity: Raloxifene hydrochloride - Not listed by IARC, NTP and OSHA.

3.COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS	Concentration
		60 mg
Raloxifene Hydrochloride, USP	82640-04-8	≅ 20.8%
Excipients	NA	≅ 79.2%

Contains no hazardous components (one percent or greater) or carcinogens (one-tenth percent or greater) not listed above.

* All Concentrations are percent by weight.

4. FIRST AID MEASURES

Inhalation: Move in to fresh air and keep at rest. For breathing difficulties, Oxygen may be necessary. Get medical attention. If breathing stops, provide artificial respiration.

Skin Contact: Wash skin thoroughly with soap and water. Get medical attention if irritation persists after washing. Remove contaminated clothing and shoes. Wash contaminated clothing before reuse. Destroy or thoroughly clean contaminated shoes.

Eye Contact: Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

Ingestion: Do not induce vomiting unless directed to do so by medical personnel. Never give liquid to an unconscious person. Get medical attention.

Notes to the Physician:
Raloxifene is an estrogen agonist/antagonist, commonly referred to as a selective estrogen receptor modulator (SERM). The biological actions of Raloxifene are largely mediated through binding to estrogen receptors. This binding results in activation of estrogenic pathways in some tissues (agonism) and blockade of estrogenic pathways in others (antagonism). The agonisticor antagonistic action of Raloxifene depends on the extent of recruitment of coactivators and corepressors to estrogen receptor (ER) target gene promotors. Raloxifene appears to act as an estrogen agonist in bone. It decreases bone resorption and bone turnover, increases bone mineral density (BMD) and decreases fracture incidence. Preclinical data demonstrate that Raloxifene is an estrogen antagonist in uterine and breast tissues. These results are consistent with findings in clinical trials, which suggest that Raloxifene hydrochloride lacks estrogen-like effects on the uterus and breast tissue.

Overdose Treatment:
There is no specific antidote for Raloxifene.

5.FIRE-FIGHTING MEASURES

Extinguishing Media: Water spray, CO2, dry chemical or alcohol resistant foam.

Unusual Fire & Explosion Hazards: Emits toxic fumes under fire conditions.

Special Fire Fighting Procedures: Self-Contained breathing apparatus and full protective clothing must be worn in case of fire.

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: Use a vacuum cleaner. If not possible, moisten dust with water before it is collected with shovel, broom or the like. Collect in containers and seal securely. For waste disposal, see section 13 of the SDS.

7.HANDLING AND STORAGE

Handling: Do not breathe dust. Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling.

Storage: Keep container tightly closed in a cool, well-ventilated place.

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: Minimize open handling. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas.

Respiratory Protection: Use a NIOSH approved respirator or an alternate approved dust mask should be used.

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: Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

Hygiene Measures: Wash skin thoroughly with soap and water.

9.PHYSICAL AND CHEMICAL PROPERTIES

Physical Properties:

Physical State: Solid

Form: Tablets

Appearance:

Raloxifene Hydrochloride Tablets, USP 60 mg – White film coated, round, biconvex tablets debossed with "**IG**" on one side and "**256**" on the other.

10. STABILITY AND REACTIVITY

Possibility of hazardous reactions: Stable

Conditions to avoid: Excessive heat & Moisture.

Incompatible materials: Strong oxidizers.

Hazardous Decomposition products: Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapors.

11.TOXICOLOGICAL INFORMATION

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

Inhalation: No data available.

Ingestion: May be harmful if swallowed.

Skin Corrosion/ irritation: Rabbit, Slight irritation.

Serious eye damage/eye irritation: Rabbit, Slight irritation.

Respiratory sensitizer/Skin sensitizer: No data available.

Carcinogenicity: Animal testing did not show any carcinogenic effects.

Mutagenesis: Negative. (Genetic toxicity assays in vitro and in vivo)

Reproductive Toxicity: When male and female rats were given daily doses ≥5 mg/kg (≥0.8 times the human dose based on surface area, mg/m2) prior to and during mating, no pregnancies occurred. In male rats, daily doses up to 100 mg/kg (16 times the human dose based on surface area, mg/m2) for at least 2 weeks did not affect sperm production or quality or reproductive performance. In female rats, at doses of 0.1 to 10 mg/kg/day (0.02 to 1.6 times the human dose based on surface area, mg/m2), raloxifene disrupted estrous cycles and inhibited ovulation. These effects of raloxifene were reversible. In another study in rats in which raloxifene was given during the preimplantation period at doses ≥0.1 mg/kg (≥0.02 times the human dose based on surface area, mg/m2), raloxifene delayed and disrupted embryo implantation, resulting in prolonged gestation and reduced litter size. The reproductive and developmental effects observed in animals are consistent with the estrogen receptor activity of raloxifene.

Other information:
The most common adverse reactions (>2% and more common than with placebo) include: hot flashes, leg cramps, peripheral edema, flu syndrome, arthralgia, sweating.

12.ECOLOGICAL INFORMATION

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

Ecotoxicity: This material is moderately toxic to fish, invertebrates, and green algae, but practically non-toxic to microorganisms.

Acute toxicity (Aquatic invertebrates): It has a low potential to bio concentrate in aquatic organisms and is not persistent in the environment.

Bioaccumulation: No data available.

Mobility: No data available.

13.DISPOSAL CONSIDERATIONS

Waste Disposal: Dispose of waste must be in accordance with all applicable Federal, State and local laws.

Measures for Avoidance and Recovery: Incineration is the most effective method of disposal in most instances. Do not allow runoff to sewer, waterway or ground. Operations that involve the crushing or shredding of waste materials or returned goods should take into account recommended exposure limits where they exist.

14.TRANSPORT INFORMATION

DOT: Not Regulated

IMDG: Not regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

15.REGULATORY INFORMATION

Stated regulatory information chosen primarily for possible usage of InvaGen 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.

U.S. Regulatory Information

CERLA Hazardous Substance List (40 CFR 302.4): None

TSCA : None

SARA Title III

Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A): None

Section 313 Toxic Release Inventory (40 CFR 372): None

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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