SAFETY DATA SHEET (SDS)

Raloxifene Hydrochloride Tablet USP, 60 mg

Revision Date: 20-April-2022 Version 2.0

1. IDENTIFICATION

Product Name: Raloxifene Hydrochloride Tablet USP**,** 60 mg

Product Information: Raloxifene Hydrochloride

Company Name: Cadila Pharmaceuticals Limited

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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

Chemical Name: 6-hydroxy-2-(4-hydroxyphenyl)-3-[4-(2-piperidinoethoxy) benzoyl]benzo[b]thiophene, hydrochloride

Product Code: Not applicable

Hazardous Ingredients / Components: Not Applicable

CAS No.: 82640-04-8

Other Components:

Inactive Ingredients	CAS No.
Lactose Monohydrate	10039-26-6
Lactose Anhydrous	
Crospovidone	9003-39-8
Povidone	25655-41-8
Polysorbate 80	9005-65-6
Opadry White	889676-18-0
Magnesium stearate	557-04-0

4. FIRST – AID MEASURES

- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.

- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed**

  May cause anemia, cough, CNS depression, drowsiness, headache, heart damage, lassitude

  (weakness, exhaustion), liver damage, narcosis, reproductive effects, teratogenic effects. No further relevant information available.

- **Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

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

Protective precautions, Protective Equipment and Emergency Procedures: Avoid raising and breathing dust, and provide adequate ventilation.

As conditions warrant, wear a NIOSH approved (or equivalent) self-contained breathing apparatus, or respirator, and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves).

Environmental precautions: Take steps to avoid release into the environment, if safe to do so.

Methods and Material for Containment and Cleaning Up: Contain spill and collect, as appropriate. Transfer to a chemical waste container for disposal in accordance with local regulations.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid breathing dust/fume/gas/mist/vapours/spray.

Avoid prolonged or repeated exposure.

Conditions for safe storage, including any incompatibilities: Keep container tightly closed.

Store in accordance with information listed on the product insert.

Storage: Store at 20° to 25°C (68° to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].

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

Raloxifene Hydrochloride Tablet USP, 60 mg:

White to off white, oval shaped film coated tablet, debossed with "C79" on one side and plain on other side.

10. STABILITY AND REACTIVITY

Reactivity: No reactivity hazards known.

Chemical Stability: Stable at normal conditions.

Possibility of hazardous reaction: No dangerous reaction known under conditions of normal use.

Conditions to Avoid: None known.

Incompatibilities with Other Materials: Strong oxidizing.

Hazardous Decomposition Product(s): NOx, SOx, Cl. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. TOXICOLOGY INFORMATION

- **Acute toxicity:** Oral TDLO (woman): 36 mg/kg/30D (intermittent); Oral TDLO (mouse): 588 mg/kg/84W (continuous); Oral TDLO (mouse): 3260 mg/kg/2W (continuous);

Intraperitoneal TDLO (rat): 12.5 mg/kg/5D (intermittent); Oral TDLO (rat): 0.03 mg/kg/3D (intermittent); Subcutaneous TDLO (rat): 50 µg/kg/3D (intermittent)

- **Skin corrosion/irritation:** No data available
- **Serious eye damage/eye irritation:** No data available
- **Aspiration hazard:** No data available
- **Specific target organ toxicity - single exposure:** No data available
- **Specific target organ toxicity - repeated exposure:** No data available
- **Respiratory and/or skin sensitization:** No data available
- **Carcinogenicity:**

  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.

  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.

  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.
- **Reproductive toxicity:** Investigated as a reproductive effector
- **Germ cell mutagenicity:** No data available
- **Signs and symptoms of exposure:** To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.
- **RTECS#:** PC4956925

12. ECOLOGICAL INFORMATION

Toxicity	Avoid release into the environment. Runoff from fire control or dilution water may cause pollution.
Persistence and degradability	No data available
Bioaccumulative potential	No data available
Mobility in soil	No data available
Other adverse effects	No data available

13. DISPOSAL CONSIDERATIONS

Waste disposal method: Dispose in accordance with local, provincial/state, and federal regulations.

14. TRANSPORT INFORMATION

UN number	No data available	
UN proper shipping name		
	DOT	Not dangerous goods
	ADR/RID	Not dangerous goods
	IMDG	Not dangerous goods
	IATA	Not dangerous goods
Transport hazard class(es)	No data available	
Transport hazard class(es)	No data available	
Packing group	No data available	
Environmental hazards	No data available	
Special precautions	No data available	

15. OTHER INFORMATION

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. 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.

Cadila Pharmaceutical Limited shall not be held liable for any damage resulting from handling or from contact with the above product.

Cadila Pharmaceutical Limited reserves the right to revise this SDS.