



Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2020

Introduction Type: New Item

Final Version

Date:

| PRODUCT INFORMATION | | | |
|---|---|------------------|--|
| Company Name: | Modavar Pharmaceuticals LLC (U.S. Agent for Cadila Pharmaceuticals Limited) | | Application: ANDA |
| Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): | 211324 | | |
| DUNS: | 858949204 | | |
| Proprietary Name (if Applicable) and Established Name: | Raloxifene Hydrochloride Tablets, USP 60mg | | |
| Selling Unit NDC: | 72241-010-05 | Unit of Use NDC: | UPC: 372241010057 |
| UDI | | CVX Code: | MX Code: |
| Description: | Raloxifene Hydrochloride Tablets, USP 60mg 100s | | |
| Active Ingredient(s): | Raloxifene Hydrochloride | | |
| URL for Additional Product Information: | www.modavar.com | | |
| Address: | 1016 16th St., NW, Suite 602 | Address 2: | |
| City: | Washington | State: | DC |
| Key Contact: | Lewis "Lew" Soars | Zip: | 20036 |
| Phone Number: | (202) 868-2391 | Email: | Lewis@Modavar.com |
| Product Therapeutic Classification: | ESTROGEN AGONIST/ANTAGONIST | | |
| | | Fax: | (202)355-9784 |

| SPECIAL HANDLING AND STORAGE REQUIREMENTS* | |
|--|--|
| a. Temperature – Indicate the USP temperature range for this product. | |
| Temperature Range | Controlled Room – between 20 and 25 C (68° – 77° F) |
| Other Temperature Range Requirement (write in) | |
| Notes | |
| Is this product to be shipped to customers on ice? | <input type="checkbox"/> No |
| Is this product to be shipped to customers on dry ice? | <input type="checkbox"/> No |
| b. Contact for temperature excursion questions: | |
| Name: | Customer Service |
| Number: | 800-688-4697 |
| Group E-mail: | ModavarCS@Eversana.com |
| c. Special regulations for product in any states? | |
| Special returns requirements for this product? | <input type="checkbox"/> No |
| d. Store product (unit of sale) upright? | |
| Protect product (unit of sale) from light? | <input type="checkbox"/> No |
| e. Shelf life: | |
| Initial shelf life at launch (if different): | <input type="text" value="24"/> Months |

| ADDITIONAL PRODUCT INFORMATION | | PRODUCT DESCRIPTION INFORMATION | |
|---|------------------------------|--|--|
| The product is? a legend device? | <input type="checkbox"/> No | Is the Product... Direct And Drop-Ship | <input type="checkbox"/> Neither |
| if yes, enter class # a product kit? | <input type="text"/> | Orphan Drug Status | <input type="text"/> |
| if yes, list NDCs of component parts reverse numbered? | <input type="text"/> | FDA Approval Status | <input type="text"/> |
| co-licensed? | <input type="checkbox"/> No | Allergens Present | See Package Insert - patient specific |
| latex-free? | <input type="checkbox"/> Yes | Country of Origin | India |
| preservative-free? | <input type="checkbox"/> Yes | Is this product covered under the Trade Agreements Act (TAA)? | <input type="checkbox"/> No |
| correctional institution block? | <input type="checkbox"/> No | | |
| opioid? | <input type="checkbox"/> No | | |
| Cannabinoid? | <input type="checkbox"/> No | | |
| If Unit Dose, is item bar coded to unit dose for hospital scanning? | <input type="checkbox"/> | | |
| If Unit Dose, indicate NDC here: | <input type="text"/> | | |
| | | Size: | 100 |
| | | Strength: | 60mg |
| | | Dosage Form: | Tablet |
| | | Product Shape: | Oval |
| | | Product Color: | white to off-white, film coated |
| | | Product Imprint: | debossed 'C79' one side; plain on the other |

| ORDER INFORMATION | |
|--|---|
| Unit of Sale | What is the NDC selling unit? |
| <input checked="" type="checkbox"/> Bottle | 1 bottle of 100 tablets |
| <input type="checkbox"/> Box/Carton | (Write-in, e.g. 1 Box of 10 Vials) |
| <input type="checkbox"/> Ampule | |
| <input type="checkbox"/> Glass | Minimum order quantity? <input type="checkbox"/> Yes |
| <input type="checkbox"/> Tube | |
| <input type="checkbox"/> Vial Liquid Sgl | |
| <input type="checkbox"/> Vial Liquid Multi | If Yes, how many of which package type? |
| <input type="checkbox"/> Vial Powder Sgl | <input type="text" value="24"/> Each |
| <input type="checkbox"/> Vial Power Multi | <input checked="" type="checkbox"/> Inner/Carton/Pack |
| <input type="checkbox"/> Other: Write In | <input type="text"/> |
| | <input type="text"/> |

| FOR GENERIC DRUG PRODUCTS | |
|--|---|
| I. Orange Book Rating: | AB <input type="checkbox"/> Authorized Generic <input type="checkbox"/> *If Authorized Generic, other section fields are not applicable |
| II. Generic Equivalent to What Brand?: | Evista® |

| PHARMACY ORDER / BILL UNIT | |
|-------------------------------------|--|
| Rec. sell unit to customer? | Rx billing unit to pharmacy: |
| <input type="text" value="1 pill"/> | <input checked="" type="checkbox"/> Each |
| (Write-in, e.g. 1 Vial) | <input type="checkbox"/> Gram |
| | <input type="checkbox"/> Milliliter |

| DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION | | |
|--|------------------------------|---|
| Does supplier meet DSCSA definition of manufacturer? | <input type="checkbox"/> Yes | GLN: 0372241000003 |
| Is product exempt from DSCSA? | <input type="checkbox"/> No | |
| If yes, select exemption: Other exemption - Write in: | <input type="text"/> | |
| Is product repackaged? | <input type="checkbox"/> No | If Yes, was original product purchased direct from mfr? |
| Is product sold by manufacturer's exclusive distributor? | <input type="checkbox"/> No | If yes, attach documentation from FDA. |
| Has FDA granted waiver/exception/exemption for product? | <input type="checkbox"/> No | |

| ITEM AND PACKING INFORMATION | | | | | | |
|-------------------------------|-------------|------------------------|-------|--------|---------------|-----------|
| Item/Each: | Weight Lbs. | Dimensions (US msmts.) | | | Volume (Cube) | # Pieces: |
| | | Depth | Width | Height | | |
| Item/Each: | 0.11 | 1.57 | 1.57 | 2.95 | 7.32 | 1 |
| Box/Carton/Bundle/Inner Pack: | 4.19 | 11.02 | 7.4 | 4.33 | 353.20 | 24 |
| Case: | 16.75 | 15.75 | 11.89 | 9.45 | 1769.68 | 96 |
| Pallet: | 555.60 | 47.24 | 39.37 | 44.09 | 82015.91 | 3456 |

| GTIN AND HIBCC PRODUCT INFORMATION | | | | |
|--|----------|-------|----------------|---------------------|
| Saleable Unit of Measure | Quantity | HIBCC | GTIN-14 | Unit of Use GTIN-14 |
| <input checked="" type="checkbox"/> Item/Each | 1 | | 00372241010057 | |
| <input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack | 24 | | 20372241010051 | |
| <input checked="" type="checkbox"/> Case | 96 | | 40372241010055 | |
| <input checked="" type="checkbox"/> Pallet | 3456 | | 50372241010052 | |
| | | | | |
| | | | | |

| COST INFORMATION | | WHOLESALE USE ONLY: | |
|-------------------------|----------|---------------------|--|
| Regular Cost | | Vendor #: | |
| Invoice Cost (WAC) (\$) | \$40.00 | Whsl. Code #: | |
| As of date: | 8/1/2022 | Fineline Code: | |

*Please provide any additional information on page 2.

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING AND BARCODE.

See new p. 3 for Designated Drop Ship Only.

Signature:

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For Designated Drop Ship Only Products, Please Use Page 3

| MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION | |
|---|--|
| <p>Is this product (check all that apply):</p> <p>a. Cytotoxic? No</p> <p>b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? No Is the product a CA Prop 65 reproductive toxicant? No Does the product label bear a CA Prop 65 warning? No</p> <p>c. Contact Hazard? No</p> <p>d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) No</p> <p>e. Does the product contain DEHP? No</p> <p>Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? No</p> <p>Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS) Yes</p> <p>a. UN/Identification Number <input type="text" value="UN3077"/></p> <p>b. Proper Shipping Name <input type="text" value="Environmentally hazardous substances, solid, n.o.s."/></p> <p>c. DOT Hazard Class <input type="text" value="9"/></p> <p>d. Packing Group <input type="text" value="III"/></p> <p>e. Inhalation Hazard? No</p> <p>Is the product restricted for air shipment? If so, indicate restriction:</p> <p><input type="checkbox"/> Passenger <input type="checkbox"/> Cargo <input checked="" type="checkbox"/> Passenger & Cargo</p> <p>Is this a reportable quantity? No RQ Threshold: <input type="text"/></p> <p>Is this a marine pollutant? Yes</p> <p>Is this product shipped utilizing an authorized DOT exception or Special Permit? No (if yes, identify method below)</p> <p><input type="checkbox"/> Limited Quantity <input type="checkbox"/> Consumer Commodity, ORM-D <input type="checkbox"/> Small Quantity (49 CFR 173.4) <input type="checkbox"/> Special Permit; DOT-SP <input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101); SP# <input type="text"/></p> | <div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">SDS Hazard Classification</div> <p><input type="checkbox"/> Organic <input type="checkbox"/> Corrosive</p> <p><input type="checkbox"/> Inorganic <input type="checkbox"/> Oxidizer</p> <p><input type="checkbox"/> Steroid/Androgen <input type="checkbox"/> Contact Hazard</p> <p><input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input type="text"/></p> <p>Is the product a NIOSH hazardous drug? No If yes, indicate which: <input type="text"/></p> |
| <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? No</p> | <div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">Hazardous Waste Identification</div> <p>EPA Hazardous Waste Code: <input type="text"/> Waste Characteristics: <input type="text"/></p> |
| <p>Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS) Yes</p> <p>a. UN/Identification Number <input type="text" value="UN3077"/></p> <p>b. Proper Shipping Name <input type="text" value="Environmentally hazardous substances, solid, n.o.s."/></p> <p>c. DOT Hazard Class <input type="text" value="9"/></p> <p>d. Packing Group <input type="text" value="III"/></p> <p>e. Inhalation Hazard? No</p> | <div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">REMS or REGISTRY RESTRICTIONS</div> <p>Is there a REMS on this product? No</p> <p>If Yes, is it managed with a pharmacy registry? <input type="text"/></p> <p>Website URL: <input type="text"/></p> <p>Med Guide Required No</p> <p>Limited Distribution Requirement No</p> <p>Comments / Details: (For example, iPledge program?) <input type="text"/></p> <p>REMS: No</p> <p>REMS Program Manager Name: <input type="text"/> Phone: <input type="text"/></p> <p>Supplier Manages REMS registry exclusively: <input type="text"/></p> <p>Wholesale distributor support: <input type="text"/></p> <p>Provider Name: <input type="text"/> DEA #: <input type="text"/></p> <p>Site Enrollment Number assigned by Supplier: <input type="text"/> PCPDP#: <input type="text"/></p> <p>NPI #: <input type="text"/></p> <p>Comments <input type="text"/></p> <p>Registry: No</p> <p>Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/></p> <p>Comments <input type="text"/></p> |
| <div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">ADD'L STORAGE INFORMATION</div> <p>Is the Product... Controlled Substance? No Controlled Substance Code <input type="text"/></p> <p>Controlled by State(s)? No Listed Chemical (List I or II) No</p> <p>ARCOS Reportable? No If yes, indicate which: <input type="text"/></p> <p>Schedule No. <input type="text"/> Is it a scheduled listed chemical product?: No</p> | <div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">RETURN INSTRUCTIONS</div> <p>Contact tel. # if product received damaged: <input type="text" value="800-688-4697"/></p> <p>Is product returnable for credit: Yes</p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? No</p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p> |
| <div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">CLASS OF TRADE RESTRICTION:</div> <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes</p> <p>Restricted to retail pharmacy only: No</p> <p>Restricted to hospital, clinics, and physician offices only: No</p> <p>Restricted from US territories? (explain in comments) No</p> <p>Comments: <input type="text"/></p> | <div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">MISCELLANEOUS NOTES and/or Image of Product Barcode:</div> <p><input type="text"/></p> |



Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2021

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

| Order Method for Designated Drop Ship Product | Standard Order Receipt and Processing |
|---|---|
| Purchase orders may be accepted by: a. EDI <input type="checkbox"/> b. Autofax <input type="checkbox"/> c. Fax <input type="checkbox"/> d. Phone only <input type="checkbox"/> e. Supplier Web Site only <input type="checkbox"/> Minimum Order Quantity: <input type="text"/> Supplier's Customer Service Number: <input type="text"/> Contracted 3PL company / contact #: <input type="text"/> Name: <input type="text"/> Phone: <input type="text"/> | Purchase order daily receipt cut off time by supplier Cut off time: <input type="text"/> Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days Ships same day for next day receipt: <input type="checkbox"/> Ships for second day receipt: <input type="checkbox"/> Ships regular ground for 3-10 days receipt: <input type="checkbox"/> |
| Expedited Freight Charges or Other Designated Drop Ship Fees: | Overnight and Priority Overnight PO Processing |
| Expedited freight fees billed with each order: <input type="text"/> Drop Ship service fee billed with each order: <input type="text"/> Drop Ship miscellaneous fees billed: <input type="text"/> Comments: <input type="text"/> | Overnight receipt available: <input type="checkbox"/> PO Receipt cut off time: <input type="text"/> Days of week overnight is available: <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday Priority Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Saturday Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Order receipt method: <input type="text"/> Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="text"/> Overnight Fees apply: <input type="checkbox"/> Other fees apply: <input type="checkbox"/> |
| Class of Trade Restriction: | |
| No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Restricted to retail pharmacy only: <input type="checkbox"/> Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> Restricted from US territories? (explain in comments) <input type="checkbox"/> Comments: <input type="text"/> | |
| Other Data Information Required to Process PO: | Return Instructions |
| Patient Procedure Date: <input type="text"/> Physician Name: <input type="text"/> Physician/Clinic Phone #: <input type="text"/> Physician State License #: <input type="text"/> Physician/Clinic DEA #: <input type="text"/> Physician/Clinic Specialty: <input type="text"/> | Contact # if product is received damaged: <input type="text"/> Is product returnable for credit: <input type="checkbox"/> URL/Link to returns policy: <input type="text"/> Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> If so, which states? Other requirements? Comments? <input type="text"/> |
| Miscellaneous Notes: | |
| <input type="text"/> | ADDITIONAL INFORMATION Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/> |