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

Version 2021 | Introduction Type: New Item | [ ] Final Version | Date: 8/25/2023

## PRODUCT INFORMATION

| | |
|---|---|
| Company Name: | XIROMED LLC |
| Application: | ANDA |
| Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): | 216209 |
| Medical Device Class, if applicable: | |
| DUNS: | 790387927 |
| Proprietary Name (If Applicable) and Established Name: | Ramelteon Tablet |
| Selling Unit NDC: | 70700-272-30 |
| Unit of Use NDC: | |
| UPC: | 370700272305 |
| UDI | |
| CVX Code: | |
| MVX Code: | |
| Description: | Ramelteon Tablet, 8mg - 30ct bottle |
| Active Ingredient(s): | Ramelteon |
| URL for Additional Product Information: | www.xiromed.com |
| Address: | 180 Park Avenue |
| Address 2: | #101 |
| City: | Florham Park |
| State: | NJ |
| Zip: | 07932 |
| Key Contact: | David Hernandez |
| Email: | david.hernandez@xiromed.com |
| Phone Number: | 844-947-6633 |
| Fax: | 862-286-0932 |
| Product Therapeutic Classification: | |

## ADDITIONAL PRODUCT INFORMATION

| | |
|---|---|
| The product is? | |
| a legend device? | No |
| if yes, enter class # | |
| a product kit? | No |
| if yes, list NDCs of component parts | |
| reverse numbered? | No |
| co-licensed? | No |
| latex-free? | Yes |
| preservative-free? | Yes |
| correctional institution block? | Yes |
| opioid? | No |
| Cannabinoid? | No |
| If Unit Dose, is item bar coded to unit dose for hospital scanning? | |
| If Unit Dose, indicate NDC here: | |
| Is the Product... | Direct-Ship Only |
| Is the Product... | Neither |
| Orphan Drug Status | |
| FDA Approval Status | |
| Allergens Present | |
| Country of Origin | USA |
| Is this product covered under the Trade Agreements Act (TAA)? | Yes |

## PRODUCT DESCRIPTION INFORMATION

| | |
|---|---|
| Size: | 7 mm diameter |
| Strength: | 8 mg |
| Dosage Form: | Tablets |
| Product Shape: | Round |
| Product Color: | pale orange, yellow |
| Product Imprint: | debossed with "C" on one s |

## FOR GENERIC DRUG PRODUCTS

[ ] Authorized Generic *If Authorized Generic, other section fields are not applicable

I. Orange Book Rating: AB

II. Generic Equivalent to What Brand?: Rozerem

## DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

| | |
|---|---|
| Does supplier meet DSCSA definition of manufacturer? | Yes |
| Is product exempt from DSCSA? | No |
| If yes, select exemption: | |
| Other exemption - Write in: | |
| Is product repackaged? | No |
| Is product sold by manufacturer's exclusive distributor? | No |
| Has FDA granted waiver/exception/exemption for product? | No |
| If yes, attach documentation from FDA. | |
| GLN: | 370700000007 |
| GCP: | |
| If yes, was original product purchased direct from mfr? | |
| Provide source manufacturer for repackaged product | |

## GTIN AND HIBCC PRODUCT INFORMATION

| | Saleable Unit of Measure | Saleable Quantity | HIBCC | GTIN-14 | Unit of Use GTIN-14 |
|---|---|---|---|---|---|
| x | Item/Each | 1 | | 00370700272305 | |
| | Box/Carton/Bundle/Inner Pack | | | | |
| x | Case | 24 | | 10370700272302 | |
| | Pallet | | | | |

## 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) | None |
| Notes | |
| Is this product to be shipped to customers on ice? | No |
| Is this product to be shipped to customers on dry ice? | No |

b. Contact for temperature excursion questions:

| | |
|---|---|
| Name: | Vipul Gandhi |
| Number: | 973-953-7867 |
| Group E-mail: | vipul.gandhi@xiromed.com |

| | |
|---|---|
| c. Special regulations for product in any states? | No |
| Special returns requirements for this product? | No |
| d. Store product (unit of sale) upright? | Yes |
| Protect product (unit of sale) from light? | No |
| e. Shelf life: | 24 Months |
| Initial shelf life at launch (if different): | 24 Months |

## ORDER INFORMATION

Unit of Sale

| | |
|---|---|
| | Bottle |
| x | Box/Carton |
| | Ampule |
| | Glass |
| | Tube |
| | Vial Liquid Sgl |
| | Vial Liquid Multi |
| | Vial Powder Sql |
| | Vial Power Multi |
| | Other: Write In |

What is the NDC selling unit?

1 Bottle of 30 Tablets

(Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity?

If Yes, how many of which package type?

| | |
|---|---|
| 24 | Each |
| | Inner/Carton/Pack |
| | Case |

## PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?

1 Bottle of 30 Tablets

(Write-in, e.g. 1 Vial)

Rx billing unit to pharmacy:

| | |
|---|---|
| x | Each |
| | Gram |
| | Milliliter |

## ITEM AND PACKING INFORMATION

| | Weight Lbs. | Dimensions (US msmts.) Depth | Width | Height | Volume (Cube) | Saleable # Pieces |
|---|---|---|---|---|---|---|
| Item/Each: | 0.08 | 1.74 | 1.74 | 3.62 | 10.959912 | 1 |
| Box/Carton/Bundle/ Inner Pack: | | | | | 0 | |
| Case: | 2 | 11.38 | 7.94 | 4.25 | 384.0181 | 24 |
| Pallet: | | | | | 0 | |

## COST INFORMATION

| | |
|---|---|
| Regular Cost | |
| Invoice Cost (WAC) ($) | $42.50 |
| As of date: | |

## WHOLESALER USE ONLY:

| | |
|---|---|
| Vendor #: | |
| Whsl. Code #: | |
| Fineline Code: | |

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

*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature:

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

Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

## MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

| | |
|---|---|
| a. Cytotoxic? | No |
| 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 |
| c. Contact Hazard? | No |
| d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) | Yes |
| e. Does the product contain DEHP? | No |
| Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) | No |
| a. UN/Identification Number | |
| b. Proper Shipping Name | |
| c. DOT Hazard Class | |
| d. Packing Group | |
| e. Inhalation Hazard? | No |
| Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS) | No |
| a. UN/Identification Number | |
| b. Proper Shipping Name | |
| c. DOT Hazard Class | |
| d. Packing Group | |
| e. Inhalation Hazard? | No |
| Is the product restricted for air shipment? If so, indicate restriction: | No |

- ☐ Passenger
- ☐ Cargo
- ☐ Passenger & Cargo

| | |
|---|---|
| Is this a reportable quantity? | No |
| RQ Threshold: | |
| Is this a marine pollutant? | No |

Is this product shipped utilizing an authorized DOT exception or Special Permit?

☐ (if yes, identify method below)

- ☐ Limited Quantity
- ☐ Consumer Commodity, ORM-D
- ☐ Small Quantity (49 CFR 173.4)
- ☐ Special Permit; DOT-SP
- ☐ Special Provision (listed in Column 7 of 49 CFR 172.101);

SP#

### SDS Hazard Classification

- ☐ Organic
- ☐ Inorganic
- ☐ Steroid/Androgen
- ☐ Corrosive
- ☐ Oxidizer
- ☐ Contact Hazard

| | |
|---|---|
| Does the product have an Aerosol class? If yes, identify NFPA Storage Level: | |
| NFPA Storage Level: | |
| Is the product a NIOSH hazardous drug? | No |
| If yes, indicate which: | |

### Hazardous Waste Identification

| | | | |
|---|---|---|---|
| EPA Hazardous Waste Code: | | Waste Characteristics | |

### REMS or REGISTRY RESTRICTIONS

| | |
|---|---|
| Is there a REMS on this product? | No |
| If Yes, is it managed with a pharmacy registry? | |
| Website URL: | |
| Med Guide Required | |
| Limited Distribution Requirement | |
| Comments / Details: (For example, iPledge program?) | |

**REMS:**

| | | | |
|---|---|---|---|
| REMS Program Manager Name: | | Phone: | |
| Supplier Manages REMS registry exclusively: | | | |
| Wholesale distributor support: | | | |
| Provider Name: | | DEA #: | |
| Site Enrollment Number assigned by Supplier: | | NCPDP#: | |
| | | NPI #: | |
| Comments | | | |

**Registry:**

| | | | |
|---|---|---|---|
| Registry Program Contact Name: | | Phone: | |
| Comments | | | |

### ADD'L STORAGE INFORMATION

Is the Product…

| | | | |
|---|---|---|---|
| Controlled Substance? | No | Controlled Substance Code | |
| Controlled by State(s)? | | Listed Chemical (List I or II) | |
| ARCOS Reportable? | | If yes, indicate which: | |
| Schedule No. | | Is it a scheduled listed chemical product?: | |

### CLASS OF TRADE RESTRICTION:

| | |
|---|---|
| No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices | |
| Restricted to retail pharmacy only: | |
| Restricted to hospital, clinics, and physician offices only: | |
| Restricted from US territories? (explain in comments) | |
| Comments: | |

### RETURN INSTRUCTIONS

| | |
|---|---|
| Contact tel. # if product received damaged: | |
| Is product returnable for credit: | |
| URL/Link to returns policy: | |
| Special regulations or returns requirements for this product in certain states? | |

If so, which states? Other requirements? Comments?

### MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE

# 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

Purchase orders may be accepted by:

a. EDI
b. Autofax — Fax Number:
c. Fax — Fax Number:
d. Phone only — Phone No.:
e. Supplier Web Site only — Site Address:

Minimum Order Quantity:

Supplier's Customer Service Number:

Contracted 3PL company / contact #: Name:
Phone:

## Standard Order Receipt and Processing

**Purchase order daily receipt cut off time by supplier**

Cut off time:

Shipping lead time of PO: Hours Days

Ships same day for next day receipt:
Ships for second day receipt:
Ships regular ground for 3-10 days receipt:

## Expedited Freight Charges or Other Designated Drop Ship Fees:

Expedited freight fees billed with each order:

Drop Ship service fee billed with each order:

Drop Ship miscellaneous fees billed:

Comments:

## Overnight and Priority Overnight PO Processing

**Overnight receipt available:**

PO Receipt cut off time:

Days of week overnight is available:
- Monday
- Tuesday
- Wednesday
- Thursday
- Friday

**Priority Overnight receipt available:**

PO Receipt Cut off time:

**Saturday Overnight receipt available:**

PO Receipt Cut off time:

Order receipt method: Phone: Phone #:
Fax: Fax #:
EDI:

Overnight Fees apply:

Other fees apply:

## Class of Trade Restriction:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices
Restricted to retail pharmacy only:
Restricted to hospital, clinics, and physician offices only:
Restricted from US territories? (explain in comments)

Comments:

## Other Data Information Required to Process PO:

Patient Procedure Date:
Physician Name:
Physician/Clinic Phone #
Physician State License #
Physician/Clinic DEA #:
Physician/Clinic Specialty:

## Return Instructions

Contact # if product is received damaged:

Is product returnable for credit:

URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states?

If so, which states? Other requirements? Comments?

## Miscellaneous Notes:

## ADDITIONAL INFORMATION

Is product order for scheduled patient procedure?

Is product order for restocking purposes?