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

Version 2024 | Introduction Type: New Item | x Final Version | Date: 5/29/2026

## PRODUCT INFORMATION

| | | | | | |
|---|---|---|---|---|---|
| Company Name: | Camber Pharmaceuticals, Inc. | | | Application: | ANDA |
| Application Number for NDA/ANDA/BLA; PMA/510(k): | 210236 | | | NDA 505(b) Type: | NOT APPLICABLE |
| Medical Device Class, if applicable: | | | | | |
| DUNS: | 11-856-3719 | | | | |
| Proprietary Name (If Applicable) and Established Name: | Pomalidomide Capsules 1 mg | | | | |
| Selling Unit NDC: | 31722-770-21 | Unit of Use NDC: | 31722-770-21 | UPC: | 331722770217 |
| UDI | | CVX Code: | | MVX Code: | |
| Description: | Pomalidomide Capsules 1 mg | | | | |
| Active Ingredient(s): | Pomalidomide | | | | |
| URL for Additional Product Information: | www.camberpharma.com | | | | |
| Address: | 800 Centennial Ave, Suite 1 | | Address 2: | | |
| City: | Piscataway | State: | NJ | Zip: | 08854 |
| Key Contact: | Customer Service | Email: | customerservice@camberpharma.com | | |
| Phone Number: | 1-866-827-3647 | Fax: | 732-562-8788 | | |
| Product Therapeutic Classification: | Immunomodulatory thalidomide analogue antineoplastic agent | | | | |

## ADDITIONAL PRODUCT INFORMATION

| | | | |
|---|---|---|---|
| The product is? | | Is the Product… | Direct And Drop-Ship |
| a legend device? | No | Is the Product… | Unit of Use |
| if yes, enter class # | | Orphan Drug Status | |
| a product kit? | No | | |
| if yes, list NDCs of component parts | | FDA Approval Status | |
| reverse numbered? | No | | |
| co-licensed? | No | Allergens Present | |
| latex-free? | Yes | Barley, Gluten, Oats, Spelt, Wheat | |
| preservative-free? | Yes | | |
| correctional institution block? | No | | |
| opioid? | No | | |
| Cannabinoid? | No | Country of Origin | India |
| If Unit Dose, is item bar coded to unit dose for hospital scanning? | | Is this product covered under the Trade Agreements Act (TAA)? | No |
| If Unit Dose, indicate NDC here: | | | |

## PRODUCT DESCRIPTION INFORMATION

| | |
|---|---|
| Size: | 21 ct |
| Strength: | 1 mg |
| Dosage Form: | Hard gelatin capsule |
| Product Shape: | Capsule |
| Product Color: | Opaque white cap and opaque white body |
| Product Imprint: | Imprinted with 'H' on cap and 'P1' on body |

## 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?: | Pomalyst | | |

## DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

| | | | |
|---|---|---|---|
| Does supplier meet DSCSA definition of manufacturer? | Yes | GLN: | 0331722498975 |
| Is product exempt from DSCSA? | No | | |
| If yes, select exemption: | | GCP: | |
| Other exemption - Write in: | | | |
| Is product repackaged? | No | If yes, was original product purchased direct from mfr? | |
| Is product sold by manufacturer's exclusive distributor? | Yes | | |
| Has FDA granted waiver/exception/exemption for product? | No | Provide source manufacturer for repackaged product | |
| If yes, attach documentation from FDA. | | | |

## GTIN AND HIBCC PRODUCT INFORMATION

| | Saleable Unit of Measure | RFID tag(Y/N) | Saleable Quantity | HIBCC | GTIN-14 | Unit of Use GTIN-14 |
|---|---|---|---|---|---|---|
| x | Item/Each | N | 1 | | 00331722770217 | 00331722770217 |
| | Box/Carton/Bundle/Inner Pack | | | | | |
| x | Case | N | 12 | | 20331722770211 | |
| | 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) | Excursions permitted to 15° to 30°C (59° – 86°F) |
| 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: | Soma Raju |
| Number: | 732-529-0423 |
| Group E-mail: | somaraju@heterousa.com |

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

## ORDER INFORMATION

| Unit of Sale | | What is the NDC selling unit? | |
|---|---|---|---|
| x | Bottle | 1 Bottle of 21 Capsules | |
| | Box/Carton | (Write-in, e.g. 1 Box of 10 Vials) | |
| | Ampule | | |
| | Glass | Minimum order quantity? | Yes |
| | Tube | | |
| | Vial Liquid Sgl | | |
| | Vial Liquid Multi | If Yes, how many of which package type? | |
| | Vial Powder Sgl | 1 | Each |
| | Vial Powder Multi | | Inner/Carton/Pack |
| | Other: Write In | | Case |

## PHARMACY ORDER / BILL UNIT

| | |
|---|---|
| Rec. sell unit to customer? | |
| (Write-in, e.g. 1 Vial) | |
| HCPCS J-Code: | |

Rx billing unit to pharmacy:

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

## ITEM AND PACKING INFORMATION

| | Weight Lbs. | Dimensions (US msmts.) Depth | Width | Height | Volume (Cube) | Saleable # Pieces |
|---|---|---|---|---|---|---|
| Item/Each: | 0.06 | 1.50 | 1.50 | 2.48 | 5.58 | 1 |
| Box/Carton/Bundle/ Inner Pack: | | | | | | |
| Case: | 1.15 | 7.0 | 5.5 | 4.38 | 168.63 | 12 |
| Pallet: | | | | | | |

## COST INFORMATION

| | |
|---|---|
| Regular Cost | |
| Invoice Cost (WAC) ($) | $2,391.67 |
| As of date: | 6/9/2026 |

## 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 2024**

**For Designated Drop Ship Only Products, Please Use Page 3**

## MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

| | |
|---|---|
| Is this product (check all that apply): | |
| a. Cytotoxic? | Yes |
| 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? | Yes |
| 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? | |
| 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? | |
| 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? | |
| No (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

| | | | |
|---|---|---|---|
| x | Organic | | Corrosive |
| | Inorganic | | Oxidizer |
| | Steroid/Androgen | | Contact Hazard |

| | |
|---|---|
| Does the product have an Aerosol class? If yes, identify NFPA Storage Level: | No |
| NFPA Storage Level: | |
| Is the product a NIOSH hazardous drug? | Yes |
| If yes, indicate which: | Group 1 items (antineoplastic) |

### Hazardous Waste Identification

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

### REMS or REGISTRY RESTRICTIONS

| | | | |
|---|---|---|---|
| Is there a REMS on this product? | Yes | | |
| If Yes, is it managed with a pharmacy registry? | Yes | | |
| Website URL: | www.PS-PomalidomideREMS.com | | |
| Med Guide Required | Yes | | |
| Limited Distribution Requirement | Yes | | |
| Comments / Details: (For example, iPledge program?) | PS-Pomalidomide Shared System REMS Program | | |
| **REMS:** | Yes | | |
| REMS Program Manager Name: | Bristol Myers Squibb | Phone: | 1-888-423-5436 |
| Supplier Manages REMS registry exclusively: | No | | |
| Wholesale distributor support: | No | | |
| Provider Name: | | DEA #: | |
| Site Enrollment Number assigned by Supplier: | | NCPDP#: | |
| | | NPI #: | |
| Comments | | | |
| **Registry:** | Yes | | |
| Registry Program Contact Name: | REMS Call Center | Phone: | 1-888-423-5436 |
| Comments | | | |

### ADD'L STORAGE INFORMATION

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

### CLASS OF TRADE RESTRICTION:

| | |
|---|---|
| No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices | Yes |
| Restricted to retail pharmacy only: | No |
| Restricted to hospital, clinics, and physician offices only: | No |
| Restricted from US territories? (explain in comments) | No |
| Comments: | Distribution to validated PS-Pomalidomide REMS Certified Dispensing Locations only. |

### RETURN INSTRUCTIONS

| | |
|---|---|
| Contact tel. # if product received damaged: | 1-888-423-5436 |
| Is product returnable for credit: | No |
| URL/Link to returns policy: | contact - www.PS-PomalidomideREMS.com |
| Special regulations or returns requirements for this product in certain states? | Yes |
| If so, which states? Other requirements? Comments? | |

**Dispensed Product Returns**: Return to prescriber, pharmacy or call 1-888-423-5436 to return directly to PS-Pomalidomide REMS program. (All States)
**Non-Dispensed Product Returns:** Return directly to Camber's third party return goods processor. (All States)
**Damaged in Transit Returns (by carrier):** Return to Camber Distribution Center. (All States)

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

Release DATE

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

**Version 2024**

**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 | Yes | | |
| b. Autofax | No | Fax Number: | None |
| c. Fax | No | Fax Number: | None |
| d. Phone only | No | Phone No.: | None |
| e. Supplier Web Site only | No | Site Address: | None |

Minimum Order Quantity: 1 Bottle — Units

Supplier's Customer Service Number: 866-827-3647

Contracted 3PL company / contact #: Name: None; Phone: None

## Standard Order Receipt and Processing

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

Cut off time: 2:00 PM Monday - Thursday — Eastern

Shipping lead time of PO: Hours — 1 Days

Ships same day for next day receipt: No

Ships for second day receipt: No

Ships regular ground for 3-10 days receipt: Yes

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

Expedited freight fees billed with each order: Yes

Drop Ship service fee billed with each order: No

Drop Ship miscellaneous fees billed: No

Comments:

## Overnight and Priority Overnight PO Processing

**Overnight receipt available:** Yes

PO Receipt cut off time: 12:00 PM — Eastern

Days of week overnight is available:

- x Monday
- x Tuesday
- x Wednesday
- x Thursday
- x Friday

**Priority Overnight receipt available:** Yes

PO Receipt Cut off time: 12:00 PM

**Saturday Overnight receipt available:** Yes

PO Receipt Cut off time: 12:00 PM

Order receipt method: Phone: No (Phone #: None); Fax: No (Fax #: None); EDI: Yes

Overnight Fees apply: No

Other fees apply: No

## Class of Trade Restriction:

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

Comments: Distribution drop-ship to validated PS-Pomalidomide REMS Certified Dispensing Locations only.

## Other Data Information Required to Process PO:

| | |
|---|---|
| Patient Procedure Date: | None |
| Physician Name: | None |
| Physician/Clinic Phone # | None |
| Physician State License # | None |
| Physician/Clinic DEA #: | None |
| Physician/Clinic Specialty: | None |

## Return Instructions

Contact # if product is received damaged: 866-827-3647

Is product returnable for credit: No

URL/Link to returns policy: https://www.camberpharma.com/partner-resources/#returned-goods-policy

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

If so, which states? Other requirements? Comments?

Dispensed Product Returns: Return to prescriber, pharmacy or call 1-888-423-5436 to return directly to PS-Pomalidomide REMS program. (All States)
Non-Dispensed Product Returns: Return directly to Camber's third party return goods processor. (All States)
Damaged in Transit Returns (by carrier): Return to Camber Distribution Center. (All States)

## Miscellaneous Notes:

## ADDITIONAL INFORMATION

Is product order for scheduled patient procedure? Yes

Is product order for restocking purposes? Yes