



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

Version 2021 Introduction Type: New Item Final Version Date: 6/26/2024

PRODUCT INFORMATION **SPECIAL HANDLING AND STORAGE REQUIREMENTS***

Company Name: Camber Pharmaceuticals, Inc. Application: ANDA
 Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 212414
 Medical Device Class, if applicable:
 DUNS: 11-856-3719
 Proprietary Name (If Applicable) and Established Name: Lenalidomide Capsules 10 mg
 Selling Unit NDC: 31722-259-28 Unit of Use NDC: 31722-259-28 UPC: 331722259286
 UDI CVX Code: MVX Code:
 Description: Lenalidomide Capsules 10 mg
 Active Ingredient(s): Lenalidomide
 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: Imide immunomodulatory thalidomide analogue (cereblon modulator)

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°C 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

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device? if yes, enter class # a product kit?	<input type="checkbox"/> No	Is the Product... Direct And Drop-Ship	Size: 28 ct
if yes, list NDCs of component parts reverse numbered?	<input type="checkbox"/> No	Is the Product... Unit of Use	Strength: 10 mg
co-licensed?	<input type="checkbox"/> No	Orphan Drug Status	Dosage Form: Hard gelatin capsule
latex-free?	<input type="checkbox"/> Yes	FDA Approval Status	Product Shape: Capsule
preservative-free?	<input type="checkbox"/> Yes	Allergens Present	Product Color: Orange opaque cap and white opaque body
correctional institution block?	<input type="checkbox"/> No	Dairy and Lactose	Product Imprint: Imprinted with 'H' on cap and 'L4' on body
opioid?	<input type="checkbox"/> No	Country of Origin	India
Cannabinoid?	<input type="checkbox"/> No	Is this product covered under the Trade Agreements Act (TAA)?	<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="checkbox"/>		

ORDER INFORMATION

Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 Bottle of 28 Capsules
<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	
<input type="checkbox"/> Vial Powder Sgl	1 Each
<input type="checkbox"/> Vial Powder Multi	Inner/ Carton/Pack
<input type="checkbox"/> Other: Write In	Case

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: AB Authorized Generic *If Authorized Generic, other section fields are not applicable
 II. Generic Equivalent to What Brand?: Revlimid

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer? (Write-in, e.g. 1 Vial)
 Rx billing unit to pharmacy: Each Gram Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? Yes No
 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? Yes
 Has FDA granted waiver/exception/exemption for product? No
 If yes, attach documentation from FDA.
 GLN: 0331722498975
 GCP:
 If yes, was original product purchased direct from mfr?
 Provide source manufacturer for repackaged product

ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.09	1.60	1.60	2.90	7.42	1
Box/ Carton/ Bundle/ Inner Pack:						
Case:	2.82	9.84	6.50	4.13	264.15	24
Pallet:						

GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1		00331722259286	00331722259286
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack				
<input checked="" type="checkbox"/> Case	24		20331722259280	
<input type="checkbox"/> Pallet				

COST INFORMATION **WHOLESALE USE ONLY:**

Regular Cost
 Invoice Cost (WAC) (\$) \$20,157.36
 As of date: 5/12/2023
 Vendor #:
 Whsl. Code #:
 Finline Code:



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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? 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?
 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

Organic
 Inorganic
 Steroid/Androgen

Corrosive
 Oxidizer
 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 2 items (non-antineoplastic that meets a hazard criterion)

Hazardous Waste Identification

EPA Hazardous Waste Code: WT02, MN01, R006
 Waste Characteristics D004

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.lenalidomiderems.com

Med Guide Required Yes
 Limited Distribution Requirement Yes
 Comments / Details: (For example, iPledge program?) Must be a certified Lenalidomide REMS Program Location

REMS: Yes

REMS Program Manager Name: Bristol Myers Squibb
 Supplier Manages REMS registry exclusively: No
 Wholesale distributor support: No
 Provider Name:
 Site Enrollment Number assigned by Supplier:
 Phone: 1-888-423-5436
 DEA #:
 NCPDP#:
 NPI #:

Comments

Registry: Yes

Registry Program Contact Name: REMS Call Center
 Phone: 1-888-423-5436
 Comments Lenalidomide REMS is a shared REMS program

ADD'L STORAGE INFORMATION

Is the Product...
 Controlled Substance? No
 Controlled by State(s)? No
 ARCOS Reportable? No
 Schedule No.

Controlled Substance Code
 Listed Chemical (List I or II) No
 If yes, indicate which:
 Is it a scheduled listed chemical product?: No

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.lenalidomiderems.com

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:

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 Lenalidomide REMS program. (All States)
Non-Dispensed Product Returns: Return directly to Camber's third party return goods processor. (All States)
Damaged in Transit Returns (bv carrier): Return to Camber Distribution Center. (All States)

MISCELLANEOUS NOTES and/or Image of Product Barcode:



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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"/> Yes b. Autofax <input type="checkbox"/> Yes Fax Number: 732-562-8788 c. Fax <input type="checkbox"/> Yes Fax Number: 732-562-8788 d. Phone only <input type="checkbox"/> No Phone No.: None e. Supplier Web Site only <input type="checkbox"/> No Site Address: None Minimum Order Quantity: 1 Bottle Units Supplier's Customer Service Number: 732-529-0430 x466 or x467 Contracted 3PL company / contact #: Name: None Phone: None	Purchase order daily receipt cut off time by supplier Cut off time: 11:00 AM Monday - Thursday Eastern Shipping lead time of PO: Hours 1 Days Ships same day for next day receipt: <input type="checkbox"/> Yes Ships for second day receipt: <input type="checkbox"/> No Ships regular ground for 3-10 days receipt: <input type="checkbox"/> No
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: <input type="checkbox"/> No Drop Ship service fee billed with each order: <input type="checkbox"/> No Drop Ship miscellaneous fees billed: <input type="checkbox"/> No Comments:	Overnight receipt available: <input type="checkbox"/> No PO Receipt cut off time: 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: 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 <input type="checkbox"/> Yes Restricted to retail pharmacy only: <input type="checkbox"/> No Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> No Restricted from US territories? (explain in comments) <input type="checkbox"/> No Comments: Distribution drop-ship to validated Lenalidomide REMS Certified Dispensing Locations only.	
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: None Physician Name: None Physician/Clinic Phone #: None Physician State License #: None Physician/Clinic DEA #: None Physician/Clinic Specialty: None	Contact # if product is received damaged: 732-529-0430 x466 or x467 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? <input type="checkbox"/> 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 Lenalidomide 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? <input type="checkbox"/> Yes Is product order for restocking purposes? <input type="checkbox"/> Yes