

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

						Introduction Typ	: New Item		x Final Version			Date:	5/17	2020
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	AGE REQUIF	REMENTS*		
Company Name:	Camber Pharmac	euticals, Inc.				Application	: ANDA	a. Temperatu	re - Indicate the USP tempe	rature range for th	nis product.			
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 212414						Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)								
Medical Device Class, if applica														
DUNS:	82-677-4775							-	Other Temperature Range I	Requirement	Excursions p	ermitted to 1	5°C to 30°C	59° – 86° F)
Proprietary Name (If Applicable) a		ame: Lenali	domide Capsules 2.5mg					П	(write in)	toquiromont	Executorione p		0 0 10 00 0 1	
Selling Unit NDC:	31722-257-28	amo: Lona.	Unit of Use NDC:	:	31722-257-28	UPC: 3:	1722257282	7	Notes					
UDI			CVX Code:		1	MVX Code:		1						
Description	Langlidamida Car	naulas 2 Ema		_				-	le this was duet to be abises.		-2		No	1
Description:	Lenalidomide Cap	psules 2.5mg							Is this product to be shipped Is this product to be shipped				No	
Active Ingradient(s):	Active Ingredient(s): Lenalidomide						-	is this product to be shipped	i to customers on a	ry ice?		INO		
Active ingredient(s).					h Contact fo	r temperature excursion qu	actions:							
URL for Additional Product Inform	mation:	www.camberpharma	n com					b. Contact to	Name:	couono.	Soma Raju			
Address:		Ave (and) 800 Center				Address 2:		+	Number:		732-529-042	3		
City:	Piscataway	()			State:		ip: 08854		Group E-mail:		somaraju@h		n	
Key Contact:	Customer Service	9			Email:	customerservice@c							_	
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special re	gulations for product in any	states?			No	1
Product Therapeutic Classification	on:	Immunomodulatory	Agent					- I	Special returns requirement				*Yes	
•			-							•				I
	ADDITI	IONAL PRODUCT IN	FORMATION			PRODUCT DE	CRIPTION INFORMATION	d. Store prod	luct (unit of sale) upright?				No	1
The product is?			Is the Product	Direct And D	rop-Ship			71	Protect product (unit of sa	ile) from light?			No	i i
a legend device?		No	Is the Product	Unit of Use	- inin		28ct	e. Shelf life:	Stoot product (unit 0) Sc	,			24	Months
if yes, enter class #		140	Orphan Drug Status			Size:	2001	C. Onen me.	Initial shelf life at launch (if different):				Months
a product kit?		No	Orphan Drug Glatas				2.5mg		middle shell me at launen (ii diiici ciity.				i i i i i i i i i i i i i i i i i i i
if yes, list NDCs of		110	FDA Approval Status			Strength:				ORDER INFORM	ATION			
component parts							hard gelatin capsule							
reverse numbered?		No				Dosage Form:			Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						1 Bottle		1 bottle of 28	capsules		
latex-free?		Yes	Doiny or	nd Lactose		Product Shape:	capsule shaped, size '4'		Box/Carton		(Write-in, e.g	g. 1 Box of 1	0 Vials)	
preservative-free?		Yes	Dali y al	iu Laciose		Froduct Snape.			Ampule					
correctional institution block?		No				Product Color:	pink opaque cap/white		Glass		Minimum or	der quantity	?	Yes
opioid?		No				rioduct color.	opaque body		Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprin	H' on cap and 'L1' on		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for						body		Vial Liquid Multi		If Yes, how		ch package	type?
hospital scanning?			Is this product covered									Each		
11 -									Vial Powder Sql					
If Unit Dose, indicate NDC here:			Trade Agreements Act (No				Vial Power Multi			Inner/Carton	/Pack	
If Unit Dose, indicate NDC here:			Trade Agreements Act (TAA)?	No								/Pack	
If Unit Dose, indicate NDC here:				TAA)?	No				Vial Power Multi			Inner/Carton	/Pack	
If Unit Dose, indicate NDC here:			Trade Agreements Act (TAA)?		hadrad Carada #1	Authorized Conneis atten		Vial Power Multi Other: Write In	ADMACY ORDER		Inner/Carton	/Pack	
			Trade Agreements Act (TAA)?			Authorized Generic, other		Vial Power Multi Other: Write In	ARMACY ORDER	/ BILL UNIT	Inner/Carton Case		
I. Orange Book Rating:	AB		Trade Agreements Act (TAA)?			Authorized Generic, other ction fields are not applicable	Rec. sell unit	Vial Power Multi Other: Write In	ARMACY ORDER		Inner/Carton Case		
		Revlimid	Trade Agreements Act (TAA)?					Vial Power Multi Other: Write In Ph	ARMACY ORDER	/ BILL UNIT	Inner/Carton Case hit to pharma Each		
I. Orange Book Rating:			Trade Agreements Act (TAA)?	Auti			Rec. sell unit	Vial Power Multi Other: Write In Ph	ARMACY ORDER	/ BILL UNIT	Inner/Carton Case hit to pharma Each Gram		
I. Orange Book Rating:			Trade Agreements Act (TAA)?	Auti				Vial Power Multi Other: Write In Ph	ARMACY ORDER	/ BILL UNIT	Inner/Carton Case hit to pharma Each		
I. Orange Book Rating:	and?:	DRUG SUPPI	Trade Agreements Act (TAA)?	Auti				Vial Power Multi Other: Write In Plat to customer?	ARMACY ORDER	/ BILL UNIT Rx billing ur	Inner/Carton Case sit to pharma Each Gram Milliliter		
I. Orange Book Rating: II. Generic Equivalent to What Bra	and?:	DRUG SUPPI	Trade Agreements Act (FOR GENERIC DRUG PR	TAA)?	Aut	Se			Vial Power Multi Other: Write In Plat to customer?		/ BILL UNIT Rx billing ur	Inner/Carton Case sit to pharma Each Gram Milliliter		
I. Orange Book Rating: II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA?	and?:	DRUG SUPPI	Trade Agreements Act (FOR GENERIC DRUG PR LY CHAIN SECURITY ACT Yes	TAA)?	Auti RMATION GLN:	Se			Vial Power Multi Other: Write In PH t to customer? . 1 Vial)	I AND PACKING IN	/ BILL UNIT Rx billing ur	Inner/Carton Case hit to pharma Each Gram Milliliter	acy:	Saleahle #
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Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

MATE	RIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION				
Is this product (check all that apply):						
a. Cytotoxic?	No	SDS Hazard Classification				
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?						
Is the product a CA Prop 65 carcinogen?		x Organic	Corrosive			
Is the product a CA Prop 65 reproductive toxicant?	No	Inorganic	Oxidizer			
Does the product label bear a CA Prop 65 warning?	No	Steroid/Androgen	Contact Hazard			
2000 the product abor 200t a of throp of hamming.		Ciolola, maiogon	O STRUCK TRAZERO			
c. Contact Hazard?	Yes	Does the product have an Aerosol class? If yes,				
d. Does this product require special clean-up instructions?	Yes	identify NFPA Storage Level:				
(If yes, attach SDS with special instructions.)	100	NFPA Storage Level:				
e. Does the product contain DEHP?	No	W 1 / Otorage Level.				
·						
Is this product regulated for shipment by DOT?	No	Is the product a NIOSH hazardous drug?	Yes			
(if yes, answer a-e below and provide SDS)		If yes, indicate which:	Group 1 items (antineoplastic)			
a. UN/Identification Number						
Proper Shipping Name						
c. DOT Hazard Class		Hazardous Waste Identification				
d. Packing Group		EDALL L. W O. I. IMTOO MING BOOK	W + 21 + 1 ft 22 + 1			
e. Inhalation Hazard?	No	EPA Hazardous Waste Code: WT02, MN01, R006	Waste Characteristics D004			
Is this product regulated for shipment by IATA?	No					
(if yes, answer a-e below and provide SDS)		REMS o	r REGISTRY RESTRICTIONS			
a. UN/Identification Number						
b. Proper Shipping Name		Is there a REMS on this product?	Yes			
c. DOT Hazard Class		If Yes, is it managed with a pharmacy registry?	Yes			
d. Packing Group		Website URL:	www.lenalidomiderems.com			
e. Inhalation Hazard?	No					
Is the product restricted for air shipment? If so, indicate restriction:	No	Med Guide Required	Yes			
Passenger		Limited Distribution Requirement	Yes			
Cargo		Comments / Details: (For example, iPledge program?)	Must be a certified Lenalidomide REMS Program Location			
Passenger & Cargo		,	·			
Is this a reportable quantity? No		REMS:	Yes			
RQ Threshold:		REMS Program Manager Name:	Bristol Myers Squibb Phone: 1-888-423-5436			
Is this a marine pollutant? Yes		Supplier Manages REMS registry exclusively:	No 1-000-425-5450			
Is this product shipped utilizing an authorized DOT exception or Special Permit?		Wholesale distributor support:	No			
No (if yes, identify method below)		Provider Name:	DEA #:			
Limited Quantity		Site Enrollment Number assigned	NCPDP#:			
Consumer Commodity, ORM-D		by Supplier:	NPI #:			
Small Quantity (49 CFR 173.4)		Бу Сиррнот.	TH 1 II.			
Special Permit; DOT-SP		Comments				
Special Provision (listed in Column 7 of 49 CFR 172.101);						
SP#		Registry:	Yes			
		Registry Program Contact Name:	REMS Call Center Phone: 1-888-423-5436			
ADD'L STORAGE INFORMATION			is a shared REMS program			
		Comments Lenandonilde KLIVIC	To a strateg region			
Is the Product			ETUDN INCTRUCTIONS			
Controlled Substance? No Controlled Substance Code		R	ETURN INSTRUCTIONS			
Controlled by State(s)? No Listed Chemical (List I or II)	No		4 000 400 5400			
ARCOS Reportable? No If yes, indicate which:		Contact tel. # if product received damaged:	1-888-423-5436			
Schedule No. Is it a scheduled listed chemical product?:	No	Is product returnable for credit:	No			
CLASS OF TRADE RESTRICTION:		URL/Link to returns policy:				
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Yes	contact - www.lenali	domiderems.com			
Restricted to retail pharmacy only:	No	Special regulations or returns requirements for this product in certain states?				
Restricted to hospital, clinics, and physician offices only:	No	,	Yes			
Restricted from US territories? (explain in comments)	No	If so, which states? Other requirements? Comments?				
Comments: Distribution to validated Lenalidomide REMS Certified Dispensing Locations only	y.		1-888-423-5436 to return directly to Lenalidomide REMS program. (All States)			
		Non-Dispensed Product Returns: Return directly to Camber's third				
	OFIL ANIES	Damaαed in Transit Returns (bv carrier): Return to Camber Distribu	Jiton Center. (All States)			
MISC	ELLANEC	OUS NOTES and/or Image of Product Barcode:				



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 Desig	nated Drop Ship Product	Standard Order Receipt and Processing
Contracted 3PL company / contact #: Name: Phone:	Fax Number: 732-562-8788 Fax Number: 732-562-8788	Purchase order daily receipt cut off time by supplier Cut off time: 11:00 AM Monday - Thursday
Expedited freight fees billed with each order:	Yes	Overnight receipt available: No
Drop Ship service fee billed with each order:	No	PO Receipt cut off time:
Drop Ship miscellaneous fees billed: Comments:	No	Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday Priority Overnight receipt available:
Class of Tra	de Restriction:	PO Receipt Cut off time:
No restriction: Select YES if sold to retail pharmacy, Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices o Restricted from US territories? (explain in comments	hospitals, clinics and physician offices No No No	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information	Required to Process PO:	Return Instructions
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty: Miscelland	eous Notes:	Contact # if product is received damaged: Is product returnable for credit: 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? 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)
		ADDITIONAL INFORMATION
		Is product order for scheduled patient procedure? Is product order for restocking purposes? Yes Yes