

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

Version 2021						Introduction Type	e: New Item		x Final Version			Date:	5/28	/2024
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	AGE REQUIR	EMENTS*		
Company Name:	Camber Pharmac	euticals, Inc.				Application	: ANDA	a. Temperature	- Indicate the USP tempe	rature range for the	nis product.			
Application Number for NDA/ANI			ce):	21	6334				emperature Range	Controlled Room -		and 25 C (68	° – 77° F)	
Medical Device Class, if applicable:														
DUNS:	11-856-3719				1			· c	ther Temperature Range F	Requirement				
Proprietary Name (If Applicable) a	nd Established Na	ame: Mesa	lamine Delayed-Release Tab	lets, USP 1.2 g	· ·				(write in)	·				
Selling Unit NDC:	31722-043-12		Unit of Use NDC:		31722-043-12		31722043120	N	lotes					
UDI			CVX Code:			MVX Code:								
Description:	Mesalamine Dela	yed-Release Tablets	i. USP 1.2 a					ls ls	this product to be shipped	to customers on id	e?		No	1
		,	, 3						this product to be shipped				No	1
Active Ingredient(s):		Mesalamine, USP									•			
								b. Contact for to	emperature excursion que	estions:				
URL for Additional Product Inform		www.camberpharm	na.com						lame:		Soma Raju			
Address:	800 Centennial A	ve, Suite 1				Address 2:			lumber:		732-529-042			
City:	Piscataway				State:		Zip: 08854	Group E-mail: somaraju@heterousa.com				<u>n</u>		
Key Contact:	Customer Service 1-866-827-3647	9			Email:	customerservice@ca	amberpharma.com	c. Special regulations for product in any states?			NI.	1		
Phone Number:		A ! !! d - !-			Fax:	732-562-8788							No	-
Product Therapeutic Classification	n:	Aminosalicylate						S	pecial returns requirement	s for this product?			No	
	A DOITI	IONAL PROBLICE IN	IFORMATION.			PROPUST DE	CODIDITION INFORMATION							7
	ADDITI	IONAL PRODUCT IN	IFORMATION			PRODUCT DES	SCRIPTION INFORMATION	d. Store produc	t (unit of sale) upright?				No	_
The product is?			Is the Product	Direct-Ship (Only				rotect product (unit of sa	le) from light?			No	
a legend device?		No	Is the Product	Unit of Use		Size:	120 ct	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status					"	nitial shelf life at launch (i	if different):				Months
a product kit?		No				Strength:	1.2 g			ORDER INFORM	ATION			
if yes, list NDCs of			FDA Approval Status				Enteric-coated tablet			ORDER INFORM	IATION			
component parts reverse numbered?		No				Dosage Form:	Enteric-coated tablet	II .	Init of Sale		What is the I	NDC selling	unit?	
co-licensed?		No	Allergens Present					ll -	x Bottle		1 Bottle of 12		unit.	
latex-free?		Yes	Allergens i resent				Oval		Box/Carton		(Write-in, e.g) Vials)	
preservative-free?		Yes				Product Shape:			Ampule		(,		
correctional institution block?		No				Product Color:	Reddish brown		Glass		Minimum or	der quantity	?	Yes
opioid?		No				Product Color:			Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint	Imprinted with 'M19' in black color on one side and plain on other side		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	ınit dose for					r roduct imprint	one side and plain on other side		Vial Liquid Multi		If Yes, how I		ch package	type?
hospital scanning?			Is this product covered u						Vial Powder Sgl			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (ГАА)?	No			_	Vial Powder Multi			Inner/Carton	/Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
					A.4	hariand Canaria *If	Authorized Constitution		DU	ARMACY ORDER	/ PILL LINIT			
				_	Aut		Authorized Generic, other ection fields are not applicable			ARMACT URDER				
	AB					56	ection fields are not applicable	Rec. sell unit to	customer?	1	Rx billing ur		асу:	
II. Generic Equivalent to What Brai	nd?:	Lialda						00/-11-1	1.// - IV			Each		
		DRIIG SUBB	LY CHAIN SECURITY ACT (DSCSA) INFO	RMATION			(Write-in, e.g. 1	Vial)			Gram Milliliter		
		DRUG SUFF	ET CHAIN SECONTT ACT	DSCSA) IN O	KMATION							wiiiiiitei		
Does supplier meet DSCSA definit	tion of manufactur	rer?	Yes		GLN:	0331722498975			ITEM	AND PACKING IN	FORMATION			
Is product exempt from DSCSA?			No		0	0001122100010								
If ves. select exemption:					GCP:			1		Dimensi	ons (US msm	te \	Volume	Saleable #
other exemption - Write in:					GUF.				Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If ves was ori	ginal product purcha	sed	Item/Each:		1				
Is product sold by manufacturer's	exclusive distribu	utor?	Yes		direct from mf				0.5	2.61	2.61	4.2	28.61	1
Has FDA granted waiver/exception			No	1		e manufacturer for re	epackaged product	Box/Carton/Bur	dle/					
If yes, attach documentation from	m FDA.							Inner Pack:						
								Case:	6.65	11	8.5	5.9	551.65	12
		GT	IN AND HIBCC PRODUCT II	NFORMATION					0.00		0.0	0.0	001.00	12
								Pallet:						
Saleable Unit of Measure	S	Saleable Quantity	HIBCC		GTIN		Unit of Use GTIN-14							
X Item/Each		1			0033	1722043120	00331722043120		COST INFORMATION		,	MUOLECALI	ER USE ONL	V.
		40			2022	1722043124			COST INFORMATION		· · · · · ·	WHOLESAL	ER USE UNL	я.
Box/Carton/Bundle/Inner Pack					2033	1722043124		Regular Cost			Vendor #:			
Box/Carton/Bundle/Inner Pack X Case		12												
Box/Carton/Bundle/Inner Pack	1	12							AC) (\$)	\$533.50		#:		
Box/Carton/Bundle/Inner Pack X Case	-	12						Invoice Cost (W	AC) (\$)	\$533.50	Whsl. Code			
Box/Carton/Bundle/Inner Pack X Case		12							AC) (\$) 4/10/2024	\$533.50				
Box/Carton/Bundle/Inner Pack X Case	-	12						Invoice Cost (W		\$533.50	Whsl. Code			
Box/Carton/Bundle/Inner Pack X Case		12						Invoice Cost (W		\$533.50	Whsl. Code			
Box/Carton/Bundle/Inner Pack X Case		12	Attach copy of SAFETY DA	NTA SHEET (SI	DS) or non hazar	d letter, PACKAGE IN	SERT, LABEL AND PHOTO OF F	Invoice Cost (W As of date:	4/10/2024	\$533.50	Whsl. Code			



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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HA	ZARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	SDS Hazard Classification					
Is the product a CA Prop 65 carcinogen? Is the product a CA Prop 65 reproductive toxicant? No Does the product label bear a CA Prop 65 warning? No	x Organic Corrosive Inorganic Oxidizer Contact Hazard					
c. Contact Hazard? d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) e. Does the product contain DEHP?	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: NFPA Storage Level:					
Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name	Is the product a NIOSH hazardous drug? If yes, indicate which:					
c. DOT Hazard Class d. Packing Group	Hazardous Waste Identification					
e. Inhalation Hazard? Is this product regulated for shipment by IATA? No	EPA Hazardous Waste Code: Waste Characteristics					
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS					
a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL: Enteric-coated tablet					
Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)					
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)	REMS: REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier: No Phone: Phone: DEA #: NCPDP#: NCPDP#: NPI #:					
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments Registry: No					
	Registry Program Contact Name: Phone:					
ADD'L STORAGE INFORMATION	Comments					
Is the Product Controlled Substance? Controlled Substance Code Controlled by State(s)? ARCOS Reportable? Schedule No. 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: Is product returnable for credit: Yes					
CLASS OF TRADE RESTRICTION:	URL/Link to returns policy:					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only: No	contact - customerservice@camberpharma.com					
Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) No	Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?					
Comments:						
MISCELLANE	OUS 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 S	nip Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI		Purchase order daily receipt cut off time by supplier Cut off time:
b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	per:	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 Designa	ed Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order:		Overnight receipt available: PO Receipt cut off time:
Drop Ship miscellaneous fees billed: Comments:		Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday
		Priority Overnight receipt available:
Class of Trade Restriction		PO Receipt Cut off time:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinic Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	s and physician offices	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to F	rocess PO:	Return Instructions
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:		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?