

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

						Introduction Type:	New Item	Х	Final Version			Date:	12/19	
			PRODUCT INFORMAT	TION					SPECIAL HAN	DLING AND STOR	AGE REQUIF	EMENTS*		
Company Name:	Camber Pharmac	euticals. Inc.				Application:	ANDA	a. Temperature – Indic	cate the USP tempe	rature range for th	is product.			
Application Number for NDA/ANI	DA/BLA: PMA/510	(k): 213377	7			NDA 505(b) Type:	NOT APPLICABLE			Controlled Room -		nd 25 C (68	° – 77° F)	
Medical Device Class, if applicab		,.				(., ,,,		1				(
DUNS:	11-856-3719							Other Te	emperature Range R	Requirement	May be refrig	erated. Store	below 25° C	
Proprietary Name (If Applicable) a		me: Mesalar	mine Suppositories for recta	al use 1000 mg					rite in)		,			
Selling Unit NDC:	31722-005-30		Unit of Use NDC:			UPC: 3317	22005302	Notes	,					
UDI			CVX Code:			MVX Code:		1						
Description:	Macalamina Cunn	ositories for rectal use	1000 mg					lo thio n	roduct to be shipped	l to austamara an is	2		No	
Description.	wesaiamine Supp	ositories for rectar use	5 1000 mg						roduct to be shipped				No	
Active Ingredient(s):		Mesalamine, USP						15 0115 p	roduct to be shipped	i to customers on a	y 100 :		140	
/ touvo mg. outoni(o).		modularimo, o or						b. Contact for tempera	ature excursion que	estions:				
URL for Additional Product Inform	ation:	www.camberpharma.	.com					Name:			Soma Raju			
Address:	800 Centennial Av	re, Suite 1				Address 2:		Number	r:		732-529-042	3		
City:	Piscataway				State:	NJ Zip	08854	Group E	E-mail:		somaraju@h	eterousa.com	1	
Key Contact:	Customer Service				Email:	customerservice@cam	berpharma.com							
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special regulations	for product in any	states?			No	
Product Therapeutic Classification	1:	Aminosalicylate						Special	returns requirements	s for this product?			No	
								_						
	ADDITIO	ONAL PRODUCT INF	ORMATION			PRODUCT DESC	RIPTION INFORMATION	d. Store product (unit	of sale) upright?				No	
The product is?			Is the Product	Direct-Ship On	nly			Protect	product (unit of sal	le) from light?			No	
a legend device?		No	Is the Product	Unit Dose		Size:	30 ct	e. Shelf life:		,			24	Months
if yes, enter class #			Orphan Drug Status			Size:		Initial s	helf life at launch (i	f different):				Months
a product kit?		No	· -			Strength:	1000 mg		•	•				
if yes, list NDCs of			FDA Approval Status			Strength.				ORDER INFORM	ATION			
component parts						Dosage Form:	Suppository							
reverse numbered?		No				Dosage i oiii.		Unit of			What is the			
co-licensed?		No	Allergens Present						Bottle		1 Carton of 3			
latex-free?		Yes				Product Shape:	Bullet	x	Box/Carton		(Write-in, e.g	. 1 Box of 10) Vials)	
preservative-free?		Yes							Ampule					
correctional institution block?		No				Product Color:	Light tan to grey		Glass		Minimum or	der quantity	?	Yes
opioid?		No		1			21/2		Tube					
Cannabinoid?	all dans for	No	Country of Origin	India		Product Imprint:	N/A		Vial Liquid Sgl		W. V 1			
If Unit Dose, is item bar coded to u hospital scanning?	nit dose for	No	la thia anadusat aassand s						Vial Liquid Multi Vial Powder Sgl		If Yes, how	nany or whice Each	сп раскаде т	ype?
			Is this product covered u		No								/Dack	
If Unit Dose, indicate NDC here:		31722-005-32	Trade Agreements Act (1		No				Vial Powder Multi			Inner/Carton	Pack/	
			Trade Agreements Act (1	гаа)?	No								/Pack	
				гаа)?	No				Vial Powder Multi			Inner/Carton	/Pack	
			Trade Agreements Act (1	гаа)?		thorized Generic *If A	uthorized Generic, other		Vial Powder Multi Other: Write In	ARMACY ORDER		Inner/Carton	/Pack	
If Unit Dose, indicate NDC here:	AR		Trade Agreements Act (1	гаа)?			uthorized Generic, other on fields are not applicable	Pac sell unit to custom	Vial Powder Multi Other: Write In	ARMACY ORDER	/ BILL UNIT	Inner/Carton Case		
If Unit Dose, indicate NDC here:	AB	31722-005-32	Trade Agreements Act (1	гаа)?				Rec. sell unit to custo	Vial Powder Multi Other: Write In	ARMACY ORDER		Inner/Carton, Case it to pharma		
If Unit Dose, indicate NDC here:			Trade Agreements Act (1	гаа)?					Vial Powder Multi Other: Write In	ARMACY ORDER	/ BILL UNIT	Inner/Carton, Case it to pharma Each		
If Unit Dose, indicate NDC here:		31722-005-32	Trade Agreements Act (1	ODUCTS	Aut			Rec. sell unit to custo (Write-in, e.g. 1 Vial) HCPCS J-Code:	Vial Powder Multi Other: Write In	ARMACY ORDER	/ BILL UNIT	Inner/Carton, Case it to pharma		
If Unit Dose, indicate NDC here:		31722-005-32	Trade Agreements Act (1	ODUCTS	Aut			(Write-in, e.g. 1 Vial)	Vial Powder Multi Other: Write In PH. mer?		/ BILL UNIT Rx billing ur	it to pharma Each Gram Milliliter		
If Unit Dose, indicate NDC here:	nd?:	31722-005-32 Canasa DRUG SUPPLY	Trade Agreements Act (I FOR GENERIC DRUG PR Y CHAIN SECURITY ACT (Yes	ODUCTS DSCSA) INFORM	Aut			(Write-in, e.g. 1 Vial)	Vial Powder Multi Other: Write In PH. mer?	ARMACY ORDER	/ BILL UNIT Rx billing ur	it to pharma Each Gram Milliliter		
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Brai	nd?:	31722-005-32 Canasa DRUG SUPPLY	FOR GENERIC DRUG PRO	ODUCTS DSCSA) INFORM	Aut	secti		(Write-in, e.g. 1 Vial)	Vial Powder Multi Other: Write In PH. mer?		/ BILL UNIT Rx billing ur	it to pharma Each Gram Milliliter		
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If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Brai	nd?:	31722-005-32 Canasa DRUG SUPPLY	Trade Agreements Act (I FOR GENERIC DRUG PR Y CHAIN SECURITY ACT (Yes	DSCSA) INFORM	Aut MATION GLN:	secti		(Write-in, e.g. 1 Vial)	Vial Powder Multi Other: Write In PH. mer?	AND PACKING IN	/ BILL UNIT Rx billing ur	it to pharma Each Gram Milliliter	ісу:	Saleable #
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Brat Does supplier meet DSCSA definit Is product exempt from DSCSA? If yes, select exemption:	nd?:	31722-005-32 Canasa DRUG SUPPLY	Trade Agreements Act (I FOR GENERIC DRUG PR Y CHAIN SECURITY ACT (Yes	DSCSA) INFORM	Aut MATION GLN: GCP:	secti	on fields are not applicable	(Write-in, e.g. 1 Vial)	Vial Powder Multi Other: Write In PH. mer? Weight Lbs.	AND PACKING IN Dimensie Depth	/ BILL UNIT Rx billing ur FORMATION Ons (US msm Width	it to pharma Each Gram Milliliter ts.) Height	Volume (Cube)	Pieces
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Brain Does supplier meet DSCSA definities product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	nd?: tion of manufactur	Canasa DRUG SUPPLY er?	Trade Agreements Act (I FOR GENERIC DRUG PR Y CHAIN SECURITY ACT (Yes No No Yes	DSCSA) INFORM	Aut MATION GLN: GCP:	secti	on fields are not applicable	(Write-in, e.g. 1 Vial) HCPCS J-Code:	Vial Powder Multi Other: Write In PH. mer?	AND PACKING IN	/ BILL UNIT Rx billing ur IFORMATION Ons (US msm	it to pharma Each Gram Milliliter	icy: Volume	
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Braid Br	nd?: ion of manufactur exclusive distribu	Canasa DRUG SUPPLY er? tor?	Trade Agreements Act (I FOR GENERIC DRUG PR Y CHAIN SECURITY ACT (Yes No	DSCSA) INFORM	MATION GLN: GCP: If yes, was ori	secti	on fields are not applicable	(Write-in, e.g. 1 Vial) HCPCS J-Code: Item/Each: Box/Carton/Bundle/	Vial Powder Multi Other: Write In PH. mer? Weight Lbs.	AND PACKING IN Dimensie Depth	/ BILL UNIT Rx billing ur FORMATION Ons (US msm Width	it to pharma Each Gram Milliliter ts.) Height	Volume (Cube)	Pieces
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Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2024

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply):						
a. Cytotoxic?	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?	Inorganic Oxidizer					
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard					
c. Contact Hazard?	Does the product have an Aerosol class? If yes, No					
d. Does this product require special clean-up instructions?	identify NFPA Storage Level:					
(If yes, attach SDS with special instructions.)	NFPA Storage Level:					
e. Does the product contain DEHP?						
Is this product regulated for shipment by DOT?	Is the product a NIOSH hazardous drug?					
(if yes, answer a-e below and provide SDS)	If yes, indicate which:					
a. UN/Identification Number	ii yes, indicate which.					
b. Proper Shipping Name						
c. DOT Hazard Class	Hazardous Waste Identification					
d. Packing Group	Tidzardous Waste trentmenton					
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics					
, ,	REMS or REGISTRY RESTRICTIONS					
(if yes, answer a-e below and provide SDS) a. UN/Identification Number	REMOUT REGISTRY RESTRICTIONS					
	Is there a REMS on this product?					
b. Proper Shipping Name c. DOT Hazard Class	If Yes, is it managed with a pharmacy registry?					
d. Packing Group	Website URL:					
e. Inhalation Hazard?	Website UKL.					
Is the product restricted for air shipment? If so, indicate restriction:	Med Guide Required No					
Passenger	Limited Distribution Requirement					
Cargo	Comments / Details: (For example, iPledge program?)					
Passenger & Cargo						
Is this a reportable quantity? No	REMS: No					
RQ Threshold:	REMS Program Manager Name: Phone:					
Is this a marine pollutant? No	Supplier Manages REMS registry exclusively:					
Is this product shipped utilizing an authorized DOT exception or Special Permit?	Wholesale distributor support:					
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)	Comments					
Special Permit; DOT-SP	Comments					
Special Provision (listed in Column 7 of 49 CFR 172.101);						
SP#	Registry: No					
ADDII CTODAGE INFORMATION	Registry Program Contact Name: Phone:					
ADD'L STORAGE INFORMATION	Comments					
Is the Product						
Controlled Substance? No Controlled Substance Code	RETURN INSTRUCTIONS					
Controlled by State(s)? No Listed Chemical (List I or II) No						
ARCOS Reportable? No If yes, indicate which:	Contact tel. # if product received damaged: 1-866-827-3647					
Schedule No. Is it a scheduled listed chemical product?: No	Is product returnable for credit:					
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 - customerservice@camberpharma.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	, NO					
Restricted from US territories? (explain in comments)	If so, which states? Other requirements? Comments?					
Comments:						
MISCELLANEO	DUS NOTES and/or Image of Product Barcode:					



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	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	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:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight receipt available: PO Receipt cut off time: Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday
	Priority Overnight receipt available:
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:	PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: Phone: 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: Miscellaneous Notes:	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?
	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure? Is product order for restocking purposes?