

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

Version 2024						Introduction T	/pe: New Item	x	Final Version			Date:	3/11/	2025	
			PRODUCT INFORMA	TION					SPECIAL HAN	IDLING AND STOR	RAGE REQUI	REMENTS*			
Company Name:	Camber Pharmac	ceuticals, Inc.				Applicat	on: ANDA	a. Temperature – Inc	dicate the USP temp	erature range for t	his product.				
Application Number for NDA/AN	NDA/BLA; PMA/510)(k):	212903			NDA 505(b) Type:	NOT APPLICABLE		erature Range	Controlled Room		and 25 C (68	3° – 77° F)		
Medical Device Class, if applica	able:														
DUNS:	11-856-3719							Other	Temperature Range	Requirement	Excursions	permitted to 1	15° to 30°C (59	9° to 86°F)	
Proprietary Name (If Applicable) a		ame:	Sodium Sulfate, Potassium Sulfate	and Magnesiu	m Sulfate Oral				(write in)						
Selling Unit NDC:	31722-098-31		Unit of Use NDC:				331722098311	Notes							
UDI			CVX Code:			MVX Code:									
Description:	Sodium Sulfate, F	Potassium Sulfa	ate and Magnesium Sulfate Oral So	olution 17.5 g/3	.13 g/1.6 g per	6 ounces			product to be shippe				No		
A office to one discretion		0 - 15 16						Is this	product to be shippe	d to customers on	dry ice?		No		
Active Ingredient(s): Sodium sulfate, potassium sulfate and magnesium sulfate									b. Contact for temperature excursion questions:						
URL for Additional Product Inform	mation:	www.camberp	pharma.com					Name			Soma Raju				
Address:	800 Centennial A	ve, Suite 1				Address 2:		Numb	oer:		732-529-042	23			
City:	Piscataway				State:	NJ	Zip : 08854	Grou	p E-mail:		somaraju@	heterousa.co	<u>m</u>		
Key Contact:	Customer Service	9			Email:		camberpharma.com								
Phone Number:	1-866-827-3647				Fax:	732-562-8788			ns for product in any				No		
Product Therapeutic Classificatio	on:	Osmotic laxar	tive					Speci	al returns requiremen	ts for this product?			No		
	ADDITI	ONAL PRODU	CT INFORMATION			PRODUCTO	ESCRIPTION INFORMATION	d. Store product (un	it of sale) unright?				No	l	
The product is 2	ADDITI	SAME TRODU		Direct-Ship (Only	- RODGET L	LOOKII HON INI OKWATION	- 1		ala) from !:=b+2					
The product is? a legend device?		No	Is the Product Is the Product	Unit Dose	July		2 x 6 ounce doses	e. Shelf life:	ct product (unit of sa	aie) from light?			No 24	Months	
if yes, enter class #		INO	Orphan Drug Status	OTHE DOSE		Size:	Z X O OUTICE GOSES		shelf life at launch	(if different)			24	Months	
a product kit?		No	Orphan Drug Glatus				17.5 g, 3.13 g, 1.6 g per 6		Silen ine at launen ((ii dilicicity.				Months	
if yes, list NDCs of			FDA Approval Status			Strength:	ounce bottle			ORDER INFOR	MATION				
component parts						Dosage Form	. Clear to slighlty hazy oral								
reverse numbered?		No				Dosage i om	solution		of Sale			NDC selling			
co-licensed?		No	Allergens Present					x					ition and Mixing Co	ontainer	
latex-free?		Yes				Product Shap	e: N/A	x			(Write-in, e	.g. 1 Box of 1	0 Vials)		
preservative-free? correctional institution block?	,	Yes No					Colorless		Ampule Glass		Minimum o	rder quantity	,2	Yes	
opioid?		No				Product Colo	r: Coloness		Tube		William	ruer quantity	,·	163	
Cannabinoid?		No	Country of Origin	India			N/A		Vial Liquid Sql						
If Unit Dose, is item bar coded to u	unit dose for		,			Product Impr	int:		Vial Liquid Multi		If Yes, how	many of whi	ich package t	type?	
hospital scanning?		Yes	Is this product covered u						Vial Powder Sgl		6	Each			
If Unit Dose, indicate NDC here:		31722-098-17	7 Trade Agreements Act (ΓAA)?	No				Vial Powder Multi			Inner/Cartor	n/Pack		
								<u> </u>	Other: Write In			Case			
			FOR GENERIC DRUG PR	ODUCIS											
					A	uthorized Generic	*If Authorized Generic, other		PI	HARMACY ORDER	/ BILL UNIT				
I. Orange Book Rating:	AA						section fields are not applicable	Rec. sell unit to cus	tomer?		Rx billing u	nit to pharm	acy:		
II. Generic Equivalent to What Bra	and?:	Suprep										Each	•		
								(Write-in, e.g. 1 Vial)				Gram			
		DRUG S	SUPPLY CHAIN SECURITY ACT (DSCSA) INFO	RMATION			HCPCS J-Code:				Milliliter			
Does supplier meet DSCSA defini	nition of manufactur	rer?	Yes	7	GLN:	0331722498975			ITEN	M AND PACKING I	NFORMATIO	N			
Is product exempt from DSCSA?			No												
If yes, select exemption:					GCP:				Maintelle	Dimens	ions (US msr	nts.)	Volume	Saleable #	
Other exemption - Write in:									Weight Lbs.	Depth	Width	Height	(Cube)	Pieces	
Is product repackaged?			No			riginal product purc	hased	Item/Each:	1.3	6.25	4.75	5.9	175.16	1	
Is product sold by manufacturer's Has FDA granted waiver/exceptio			Yes No	-	direct from n			Box/Carton/Bundle/							
If yes, attach documentation fro		roduct?	NO		Provide soul	rce manuracturer to	repackaged product	Inner Pack:							
ii yoo, amaan addamamaaan iid	J 27							Case:	2.0	14.25	13	0.5	4004.40	_	
			GTIN AND HIBCC PRODUCT I	NFORMATION					8.8	14.25	13	6.5	1204.13	6	
								Pallet:							
Saleable Unit of Measure	RFID tag(Y/N)		HIBCC		GT	IN-14	Unit of Use GTIN-14								
X Item/Each	N	Quantity 1			003	331722098311									
Box/Carton/Bundle/Inner Pack	14	'			000	3022000011			OST INFORMATION			WHOLESAL	ER USE ONL	Y:	
X Case	N	6			203	331722098315									
								Regular Cost			Vendor #:				
Pallet								Invoice Cost (WAC)	(\$)	\$87.00	Whsl. Code	. 4.			
Pallet															
Pallet								As of data:	1/30/2025		Fineline Co				
Pallet								As of date:	1/30/2025						
Pallet								As of date:	1/30/2025						
Pallet			Attach copy of SAFETY DA	ATA SHEET (SI	DS) or non haza	ard letter, PACKAGE	INSERT, LABEL AND PHOTO OF								



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

Version 2024

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZ	ZARD 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	il yes, illucate willon.						
b. Proper Shipping Name							
c. DOT Hazard Class	Hazardous Waste Identification						
d. Packing Group							
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics						
Is this product regulated for shipment by IATA?	REMS or REGISTRY RESTRICTIONS						
(if yes, answer a-e below and provide SDS) a. UN/Identification Number	REMO OF REGISTRIC FIGURE						
b. Proper Shipping Name	Is there a REMS on this product?						
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:	140						
Restricted from US territories? (explain in comments)	If so, which states? Other requirements? Comments?						
Comments:							
MISCELLANE(OUS 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 Fax Number:	Purchase order daily receipt cut off time by supplier Cut off time:
c. Fax d. Phone only Phone No.:	Shipping lead time of PO: Hours Days
e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	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:	Overnight receipt available:
Drop Ship service fee billed with each order:	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, 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:	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/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?