

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

						Introduction Type:	New Item		x Final Version			Date:	10/23	3/2025
			PRODUCT INFORMA	ATION					SPECIAL HAN	DLING AND STOR	AGE REQUIF	REMENTS*		
Company Name:	Camber Pharmac	ceuticals Inc				Application:	ANDA	a Tomporatu	re - Indicate the USP tempe	rature range for t	his product			
Application Number for NDA/AN			5			NDA 505(b) Type:	NOT APPLICABLE	_ u. remperatu	Temperature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applical		(1)	·			(., ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		T		-		(
DUNS:	11-856-3719							1	Other Temperature Range F	Requirement	Excursions p	ermitted to 1	5° to 30°C (5	9° to 86°F)
Proprietary Name (If Applicable) a		ame: Gabar	entin Tablets (Once Daily),	USP 600 ma				T	(write in)				(-	,
Selling Unit NDC:	31722-092-90		Unit of Use NDC:		31722-092-90	UPC: 3317	22092906	1	Notes					
UDI			CVX Code:			MVX Code:		1						
Description:	Gabanentin Table	ets (Once Daily), USP	600 mg					Ť	Is this product to be shipped	I to customers on i	re?		No	1
Description.	Cabaponan rabi	oto (Onico Bany), Oci	000 mg						Is this product to be shipped				No	1
Active Ingredient(s):		Gabapentin, USP					†			,			1	
							b. Contact for temperature excursion questions:							
URL for Additional Product Inforn	nation:	www.camberpharma	a.com					1	Name:		Soma Raju			
Address:	800 Centennial A	ve, Suite 1				Address 2:			Number:		732-529-042			
City:	Piscataway				State: NJ Zip: 08854			Group E-mail:		somaraju@h	eterousa.con	<u>n</u>		
Key Contact:	Customer Service	9			Email: customerservice@camberpharma.com							41.6	1	
Phone Number:	1-866-827-3647				Fax: 732-562-8788			c. Special reg	gulations for product in any				*Yes	
Product Therapeutic Classificatio	on:	Anticonvulsant							Special returns requirement	s for this product?			No	
	ADDIT	IONAL PRODUCT-IN	FORMATION -			DRODUCT DEACH	PIDTION INFORMATION						NI-	1
	ADDIII	IONAL PRODUCT IN		B:		PRODUCT DESC	RIPTION INFORMATION	a. Store prod	uct (unit of sale) upright?				No]
The product is?			Is the Product	Direct-Ship C	Only	1	20.1		Protect product (unit of sa	le) from light?			No	
a legend device?		No	Is the Product	Unit of Use		Size:	90 ct	e. Shelf life:	1-14-1-1-1414	£ -1166			24	Months
if yes, enter class # a product kit?		No	Orphan Drug Status				600 mg		Initial shelf life at launch (i	f different):				Months
if yes, list NDCs of		INO	FDA Approval Status			Strength:	600 mg			ORDER INFORM	MATION			
component parts			i DA Appiovai Status				Film coated tablet			0113211111111111111				
reverse numbered?		No				Dosage Form:	Tilli codica tablet		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						x Bottle		1 Bottle of 90) Tablets		
latex-free?		Yes	_	Soy		Product Shape:	Oval		Box/Carton		(Write-in, e.	g. 1 Box of 10) Vials)	
preservative-free?		Yes	•	Suy		Product Snape.			Ampule					
correctional institution block?		No				Product Color:	Yellow		Glass		Minimum or	der quantity	?	Yes
opioid?		No							Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint:	Debossed with 'G7' on one side and 'V1' on other side		Vial Liquid Sgl					
If Unit Dose, is item bar coded to unhospital scanning?	unit dose for						side and VT on other side		Vial Liquid Multi		If Yes, how		ch package	type?
If Unit Dose, indicate NDC here:			Is this product covered to Trade Agreements Act (No				Vial Powder Sgl Vial Powder Multi		24	Each Inner/Carton	/Dook	
II Offit Dose, indicate NDC fiere.			Trade Agreements Act ((100):								IIIIIei/Carton		
			_						Other: Write In			Case		
			FOR GENERIC DRUG PE	PODUCTS				<u>J</u>	Other: Write In			Case		
			FOR GENERIC DRUG PR	RODUCTS					Other: Write In			Case		
			FOR GENERIC DRUG PR	RODUCTS		thorized Generic *If Au	uthorized Generic, other	<u> </u>		ARMACY ORDER		Case		
L Orango Rook Pating	ΔR2		FOR GENERIC DRUG PR	RODUCTS			uthorized Generic, other on fields are not applicable	Rec sell unit	PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB2	Gralise	FOR GENERIC DRUG PR	RODUCTS				Rec. sell unit		ARMACY ORDER		nit to pharma		
I. Orange Book Rating: II. Generic Equivalent to What Bra		Gralise	FOR GENERIC DRUG PR	RODUCTS					PH to customer?	ARMACY ORDER	/ BILL UNIT	nit to pharma Each		
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Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

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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? 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? Does the product label bear a CA Prop 65 warning? No	x Organic Corrosive Oxidizer Steroid/Androgen 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? Is this product regulated for shipment by DOT?	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: NFPA Storage Level: Is the product a NIOSH hazardous drug? No						
(if yes, answer a-e below and provide SDS) a. UN/dentification Number b. Proper Shipping Name	If yes, indicate which:						
c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics						
	El 711 IZZI GOLG VIGLE GOLG.						
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:						
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);	Comments						
SP#	Registry: Registry Program Contact Name: No Phone:						
ADD'L STORAGE INFORMATION	Registry Program Contact Name: Phone: Comments						
Is the Product							
Controlled Substance? No Controlled Substance Code	RETURN INSTRUCTIONS						
Controlled by State(s)? Yes 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:	Special regulations or returns requirements for this						
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) No	product in certain states? If so, which states? Other requirements? Comments?						
Comments:	This product is classified as a Schedule V controlled substance in Alabama, Kentucky, Montana, North Dakota, Tennessee, Utah, Virginia, and West Virginia.						
MISCELLANEC	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 Ship Product	Standard Order Receipt and Processing						
Purchase orders may be accepted by:		Purchase order daily receipt cut off time by supplier						
a. EDI		Cut off time:						
b. Autofax	Fax Number:							
c. Fax	Fax Number:	Shipping lead time of PO: Hours Days						
d. Phone only	Phone No.:							
e. Supplier Web Site only	Site Address:	Ships same day for next day receipt:						
Minimum Order Quantity:		Ships for second day receipt:						
Supplier's Customer Service Number:		Ships regular ground for 3-10 days receipt:						
Contracted 3PL company / contact #:	Name:							
	Phone:							
Expedited Freight Cha	arges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing						
Expedited freight fees billed with each orde	er:	Overnight receipt available:						
Drop Ship service fee billed with each orde	r:	PO Receipt cut off time:						
Drop Ship miscellaneous fees billed:		Days of week overnight is available: Monday						
Comments:		Tuesday						
		Wednesday						
		Thursday						
		Friday						
		Priority Overnight receipt available:						
Cla	ss of Trade Restriction:	PO Receipt Cut off time:						
Restricted to retail pharmacy only:	harmacy, hospitals, clinics and physician offices	Saturday Overnight receipt available: PO Receipt Cut off time:						
Restricted to retail priarmacy only. Restricted to hospital, clinics, and physiciar	o offices only	Phone:						
Restricted from US territories? (explain in c	·	Order receipt method: Fax: Fax #:						
Comments:	oninents)	EDI:						
		Overnight Fees apply:						
		Other fees apply:						
Other Data Inf	formation Required to Process PO:	Return Instructions						
Patient Procedure Date:		Contact # if product is received damaged:						
Physician Name:		Is product returnable for credit:						
Physician/Clinic Phone #		URL/Link to returns policy:						
Physician State License #		Ortigizant to rotatino policy.						
Physician/Clinic DEA #:		Special regulations or returns requirements for this product in certain states?						
Physician/Clinic Specialty:		If so, which states? Other requirements? Comments?						
	Miscellaneous Notes:							
		ADDITIONAL INFORMATION	ADDITIONAL INFORMATION					
		Is product order for scheduled patient procedure?						
		Is product order for restocking purposes?						