

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

Control   Plantencing   Plantencing   Control   Plantencing   Plante	Version 2024						Introduction 7	Type: Post Launch Change		x Final Version			Date:	7/22	//2024	
Mode Size   Mode				PRODUCT INFORMAT	TION					SPECIAL HAN	IDLING AND STOR	AGE REQUI	REMENTS*			
Total Control Control Replace Application   Total Control Co	Company Name:	Camber Pharmace	euticals, Inc.				Applica	tion: ANDA	a. Temperatu	a. Temperature – Indicate the USP temperature range for this product.						
Bigs   1982	Application Number for NDA/AN	DA/BLA; PMA/510(	(k): 20	06912			NDA 505(b) Type	NOT APPLICABLE					and 25 C (68	s° – 77° F)		
Projection   Pro	Medical Device Class, if applicat															
March   Marc											Requirement					
Control   Projection Control			ime: Pi			04700 040 00										
Recording Symbols   Page   P		31722-616-90				31722-616-90		331722616904		Notes						
Activation   Project   P	-			CVA Code.			MIVA GOUC.								1	
Authors (1996)   Property   Pro	Description:	Pregabalin Capsul	les 225 mg												-	
Court Court   Court	Active Ingredient(s):		Pregabalin							is this product to be shippe	a to customers on c	ily ice :		INU		
Winds   Marked   Ma																
Product Thereposed: Classification:   Product Thereposed:   Product Thereposed: Classification:   Product				arma.com												
Control   Cont			ve, Suite 1													
Picos   Marion   Picos   Pic							-			Group E-mail: somaraju@heterousa.com						
Special content of the product of			!						c Special rea	a Special regulations for product in any states?					1	
## ADDITIONAL PRODUCT INFORMATION   The products 137   The products 13			Anticonvulsant	neuronathic nain agent		- rux.	732-302-0700		c. opeciai reg							
Per product is 7	Froduct Therapeutic Glassification		7 ti ilicon v disant	nedropatnie pain agent						Special returns requiremen	ts for this product:			140		
Per product is 7		ADDITIO	ONAL PRODUC	T INFORMATION			PRODUCT	DESCRIPTION INFORMATION	d. Store prod	uct (unit of sale) upright?				No	1	
a le gend device? In yes, entre class # I yes, entr	The product is?				Direct-Shin (	Only					ale) from light?				i	
Service Class 8   Service Class 9   Service Clas			No				0'	90 ct	e. Shelf life:	. rotoot product (dime or or	a.o, og				Months	
Strength:    Foundation   Found				Orphan Drug Status			Size:			Initial shelf life at launch (	(if different):				Months	
System Affice of   Product Shape:   Product Color:   Pr			No				Strength:	225 mg								
Every content number er?   No   Allergenic Present   No   Corn, Sugar, Alcohol   Product Shape:   Product Shape:   Sugar Alcohol   Product Shape:   Product Shape:   Sugar Alcohol   Sugar A				FDA Approval Status							ORDER INFORM	IATION				
Locange Book Rating: Rating Book Rat			No				Dosage Form	n: Hard gelatin capsule		Unit of Sala		What is the	NDC selling	unit?		
Islant-Kree?   Yes   Corn. Sugar. Alcohol   Product Shape:   Capsile   Societion   Institution block?   Yes   Country of Origin   Use				Allergens Present					-							
preservative-free? Ves connectional institution block? No Country of Origin USA Product Color: Use this product country of Origin USA Product Imprint: Use this product country of Origin USA Product Imprint: Use this product country of Origin Use this product co	latex-free?				ar Alaabal		Deadwat Cha	Capsule						0 Vials)		
spiniot? Cannalization? No Country of Crigin Unit Dose, is tein bar coded to unit dose for Visit Equal Multi Visit Equal			Yes	Corn, Sug	ar, Alconoi		Product Sna									
Select respectage of the Packet of the Packe							Product Col	or: Light peach opaque cap and				Minimum o	rder quantity	?	Yes	
From Dose, is dem bar coded to unit dose for lost this product covered under the proposed source and from the product covered under the proposed source and the product proposed source and the product process of the				Occupation of October	LICA			Willie opaque body								
Soliable Unit of Massure Regular Cost (MAC) (S)   Soliable Regular Cost		init dose for	NO	Country of Origin	USA		Product Imp					If Voc. how	many of whi	ch nackage	tuno?	
FOR GENERIC DRUG PRODUCTS    Authorized Generic   Trade Agreements Act (TAA)?   Yes		anii dose ioi		Is this product covered up	nder the				-					on package	турс .	
Authorized Generic - THE Authorized Generic - Christophe Book Reling: Authorized Generic - Christophe Book Reling: Authorized Generic - Christophe Book Reling: B.						Yes				Vial Powder Multi			Inner/Carton	/Pack		
Authorized Generic Description of Measure Republic Plant Countries Section fields are not applicable section										Other: Write In			Case			
I. Canage Book Rating:  II. Generic Equivalent to What Brand?:    Direct Supplex Chain Security Act (OSCSA) INFORMATION				FOR GENERIC DRUG PRO	DDUCTS											
I. Canage Book Rating:  II. Generic Equivalent to What Brand?:    Lyrica   DRUG SUPPLY CHAIN SECURITY ACT (OSCSA) INFORMATION								*** * * * * * * * * * * * * * * * * * *		DI DI	IARMACY ORDER	/ DILL LINET				
Comparing Study Natural Control Equivalent to What Brand?   Lyrica   Lyri					_	Au	thorized Generic				TARMACT ORDER					
Does supplier meet DSCSA definition of manufacturer?  Yes  GDF:    Weight Lbs.   Dimensions (US mmts.)   Volume   Saleable   Foliation   F		orange book Rating:						Section fields are not applicable	Rec. sell unit	3						
Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.    HCPCS J-Code:   Milliter	II. Generic Equivalent to What Brand?:								(Write-in e.g.							
Figure   ScSA definition of manufacturer?   Yes   GLN:   0860000397957			DRUG SL	JPPLY CHAIN SECURITY ACT (I	DSCSA) INFO	RMATION			HCPCS J-Co	de:						
S product exempt from DSCSA?   No     Saleable # Form   Social product purchased   Social product pu			_										-			
Figure 1   Service   Ser		tion of manufacture	er?			GLN:	0860000397957			ITEN	M AND PACKING I	NFORMATIO	N			
Other exemption - Write in: Is product repackaged?  No If yes, was original product purchased direct from mif? Provide source manufacturer's exclusive distributor? Has FDA granted waiver/exception/exemption for product? If yes, attach documentation from FDA.    Case   2.75   10.5   7   4.5   331   24	Is product exempt from DSCSA?			No												
Item/Each  Saleable Unit of Measure RFID tag(Y/N) Saleable Quantity    X						GCP:				Weight Lbs.		•	•			
Is product sold by manufacturer's exclusive distributor?  Has FDA granted waiver/exception/exemption for product?  If yes, attach documentation from FDA.    Saleable Unit of Measure   RFID tag(Y/N)   Saleable   Cost   N   1				No		16	iniual nasalust nun	shasad	Many/Fach	-		Width	Height	(Cube)	Pieces	
Has FDA granted waiver/exception/exemption for product? If yes, attach documentation from FDA.    Saleable Unit of Measure   RFID tag(Y/N)   Saleable   Cuantity     X   Item/Each   Sox/Carton/Bundle/Inner Pack     X   Case   Sox/Carton/Bundle/Inner Pack     X   Case   Sox/Carton/Bundle/Inner Pack     X   Case   Sox/Carton/Bundle/Inner Pack     X   Das   Das   Das   Das   Das     Pallet   Das   Das   Das     Pallet   Das   Das   Das   Das     Pallet   Das   Das   Das     Pallet   Das   Das   Das   Das     Pallet   Das   Das   Das     Pallet   Das   Das   Das   Das     Pallet   Das   Das   Das     Pallet   Das   Das   Das   Das     Pallet   Das   Das   Das     Pallet   Das   Das   Das   Das     Pallet   Das   Das   Das     Pallet   Das   Das   Das   Das     Das   Das   Das   Das		evelusive distribu	itor?		-			cnased	item/Each:	0.09	1.65	1.65	3.1	8	1	
Inner Pack:					+			or repackaged product	Box/Carton/E	Bundle/						
Saleable Unit of Measure   RFID tag(Y/N)   Saleable   Quantity     X								, , , , , , , , , , , , , , , , , , , ,								
Saleable Unit of Measure   RFID tag(Y/N)   Saleable   Quantity									Case:	2.75	10.5	7	4.5	331	24	
Saleable Unit of Measure   RFID tag(Y/N)   Saleable   Quantity				GTIN AND HIBCC PRODUCT IN	IFORMATION											
N	Saleable Unit of Measure	PEID tog(V/N)	Saleable	HIBCC		GTII	N-14	Unit of Use CTIN-14	Pallet:							
X	Saleable Offit of Measure	KFID (ag(1/N)		ПІВСС		Gii	N-14	Offit of OSE G11N-14								
X Case	x Item/Each	N				003	31722616904	00331722616904								
Pallet Regular Cost Invoice Cost (WAC) (\$) As of date: 9/1/2021  Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.										COST INFORMATION			WHOLESAL	ER USE ONL	-Y:	
Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.		N	24			303	31722616905		11							
Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.	Pallet										640.50		. #-			
Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.									IIIVOICE COST	(1170) (4)	\$10.50					
									As of date:	9/1/2021		1				
									- []							
	П															
	*Please provide and additional inf	ormation	•	Attach copy of SAFETY DA	TA SHEET (SI	OS) or non haza			F PRODUCT PACK	AGING and BARCODE.						



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

#### Version 2024

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HA	AZARD 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 the product a NIOSH hazardous drug?						
Is this product regulated for shipment by DOT?  (if yes, answer a-e below and provide SDS)	Is the product a NIOSH hazardous drug?  No  If yes, indicate which:						
a. UN/Identification Number	ii yes, iiidicate wiiidi.						
b. Proper Shipping Name							
c. DOT Hazard Class	Hazardous Waste Identification						
d. Packing Group	Trazardous Traste Identification						
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics						
Is this product regulated for shipment by IATA?  No. (14 year annual and behavior of applied and applied applied and applied and applied and applied and applied and applied and applied applied and applied and applied applied applied and applied applied applied applied applied applied and applied and applied appli	DEMC DECICED V DESTRICTIONS						
(if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS						
a. UN/Identification Number	L II DELLO III LO						
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 e. Inhalation Hazard?	Website URL:						
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)							
Special Permit; DOT-SP	Comments						
Special Provision (listed in Column 7 of 49 CFR 172.101);							
SP#	Registry: No						
ARRIVATOR LOS INFORMATION	Registry Program Contact Name: Phone:						
ADD'L STORAGE INFORMATION	Comments						
Is the Product							
Controlled Substance? Yes Controlled Substance Code 2782	RETURN INSTRUCTIONS						
Controlled by State(s)? Yes Listed Chemical (List I or II) No							
ARCOS Reportable? Yes If yes, indicate which:	Contact tel. # if product received damaged: 1-866-827-3647						
Schedule No. 5 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:	product in certain states?						
Restricted from US territories? (explain in comments)	If so, which states? Other requirements? Comments?						
Comments:							
MISCELLANE	EOUS NOTES and/or Image of Product Barcode:						
*Storage of this product must abide by the federally mandated DEA requirements outlined in 21 CFR Part							
Otorage of this product must ablue by the lederally mandated DEA requirements outlined in 21 OFK Fall	(1001)2.						



## **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?