

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

Version 2024						Introduction T	ype: New Item		x Final Version			Date:	9/3/2	2024	
			PRODUCT INFORMAT	TION					SPECIAL HAN	IDLING AND STOR	AGE REQUI	REMENTS*			
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA							ion: ANDA	a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/AN	IDA/BLA; PMA/510	)(k): 21	0203			NDA 505(b) Type:	NOT APPLICABLE		Temperature Range	Controlled Room		and 25 C (68	° – 77° F)		
Medical Device Class, if applical	ble:														
DUNS:	11-856-3719								Other Temperature Range	Requirement	Excursions p	permitted to 1	5° to 30°C (59	9° to 86°F)	
Proprietary Name (If Applicable) a		ame: Ca	apecitabine Tablets, USP 150 mg	1					(write in)						
Selling Unit NDC:	31722-774-60		Unit of Use NDC:		31722-774-60	UPC: MVX Code:	331722774604		Notes						
UDI			CVX Code:			MVX Code:								-	
Description:	Capecitabine Tab	olets, USP 150 mg	9						Is this product to be shipped				No		
Active Ingredient(s): Capecitabine, USP									Is this product to be shipped to customers on dry ice?						
		temperature excursion qu	estions:												
URL for Additional Product Inform Address:		www.camberph	arma.com			Address 2:			Name:		Soma Raju	20			
City:	Piscataway	entennial Ave, Suite 1			NJ   Zip:   08854				Number: 732-529-0423  Group E-mail: somaraju@heterou				2000		
Key Contact:	Customer Service	2				Email: customerservice@camberpharma.com			Group E-mail:		Somarajuer	leterousa.cor	<u> </u>		
Phone Number:	1-866-827-3647				Fax:		732-562-8788		c. Special regulations for product in any states?			1		No	
Product Therapeutic Classificatio		Nucleoside met	tabolic inhibitor						Special returns requirement				No		
l round morapound diagonicans	•••								oposiai rotarrio roquirorriori	to for tino product.				1	
	ADDITI	IONAL PRODUC	T INFORMATION			PRODUCT I	DESCRIPTION INFORMATION	d. Store produ	ict (unit of sale) upright?				No	1	
The product is?			Is the Product	Direct-Ship (	Only				Protect product (unit of sa	ale) from light?			No	i	
a legend device?		No	Is the Product	Unit of Use	•	Sime.	60 ct	e. Shelf life:		· ., · · · · · · · · · · · · · · · ·			24	Months	
if yes, enter class #			Orphan Drug Status			Size:			Initial shelf life at launch (	if different):				Months	
a product kit?		No				Strength:	150 mg								
if yes, list NDCs of			FDA Approval Status			Ou chigan.				ORDER INFORM	IATION				
component parts		Ta a				Dosage Forn	Biconvex, film coated				Mart	NDO III			
reverse numbered? co-licensed?		No	Allarmana Drasant			_	tablet	- I I	Unit of Sale x Bottle		1 Bottle of 6	NDC selling	unit?		
latex-free?		No Yes	Allergens Present				Capsule		x Bottle Box/Carton			g. 1 Box of 1	) Viale)		
preservative-free?		Yes	Lactos	e, Dairy		Product Sha	pe: Capsule		Ampule		(vviite-iii, e.	g. I box of fi	J viais)		
correctional institution block?		No					Light peach		Glass		Minimum o	rder quantity	?	Yes	
opioid?		No				Product Cold	or:		Tube			<b></b> ,			
Cannabinoid?		No	Country of Origin	India		Product Impi	Debossed with '6' on one side		Vial Liquid Sgl						
If Unit Dose, is item bar coded to u	unit dose for					r roduct impi	and 'H' on the other side		Vial Liquid Multi				ch package t	type?	
hospital scanning?			Is this product covered u						Vial Powder Sgl		24	Each			
If Unit Dose, indicate NDC here:			Trade Agreements Act (T	AA)?	No				Vial Powder Multi Other: Write In			Inner/Carton	/Pack		
			FOR GENERIC DRUG PRO	DUOTO					Other: write in			Case			
			FOR GENERIC DRUG PRO	DDUCIS											
					Au	thorized Generic	*If Authorized Generic, other		Pŀ	IARMACY ORDER	/ BILL UNIT				
I. Orange Book Rating:	AB			_			section fields are not applicable	Rec. sell unit t				nit to pharma	acv.		
II. Generic Equivalent to What Brand?: Xeloda					Received and the design of the second of the					acy.					
iii. Generio Equitatenti o vinat Brana.						(Write-in, e.g. 1 Vial) Gram									
		DRUG SU	IPPLY CHAIN SECURITY ACT (	DSCSA) INFO	RMATION			HCPCS J-Cod				Milliliter			
				_		-			J8520						
Does supplier meet DSCSA defini	ition of manufactu	rer?	Yes No	_	GLN:	0331722498975			ITEN	AND PACKING I	NFORMATIO	N			
Is product exempt from DSCSA?			INU												
If yes, select exemption:					GCP:				Weight Lbs.		ons (US msn	•	Volume	Saleable #	
Other exemption - Write in: Is product repackaged?			No		If you	iginal product = :	shacad	Item/Each:	-	Depth	Width	Height	(Cube)	Pieces	
Is product repackaged? Is product sold by manufacturer's	avalucius distribu	utor?	Yes	-	direct from m	iginal product purd	cnased	item/Each:	0.08	1.49	1.49	2.54	5.64	1	
Has FDA granted waiver/exceptio			No No	+			r repackaged product	Box/Carton/Bu	undle/						
If yes, attach documentation from			-				. repuellagea product	Inner Pack:							
								Case:	2.4	10	6.75	4.25	286.88	24	
			GTIN AND HIBCC PRODUCT IN	NFORMATION					2.4	10	0.73	4.23	200.00	24	
								Pallet:							
Saleable Unit of Measure	RFID tag(Y/N)		HIBCC		GTI	N-14	Unit of Use GTIN-14								
x Item/Each	N	Quantity 1			003	31722774604	00331722774604								
Box/Carton/Bundle/Inner Pack	IN						000022117007		COST INFORMATION			WHOLESAL	ER USE ONL	.Y:	
X Case	N	24			203	31722774608									
Pallet								Regular Cost			Vendor #:				
								Invoice Cost (	WAC) (\$)	\$30.50	Whsl. Code				
								11	0/5/2224		Fineline Co	de:			
					-			As of date:	8/5/2024		1				
			Attach copy of SAFETY DA	TA SHEET /SI	OS) or non haza	rd letter PACKACE	INSERT, LABEL AND PHOTO O	E DRUDITICT DACKA	GING and RAPCODE						



## **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 HAZ	ARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? No Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning? No	SDS Hazard Classification  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?  No	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:  Yes  Group 1 items (antineoplastic)					
c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Hazardous Waste Identification  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:					
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? Yes 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: DEA #: NCPDP#: NPI #:					
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);	Comments					
SP#	Registry: No					
ADD'L STORAGE INFORMATION	Registry Program Contact Name: Phone:					
	Comments					
Is the Product  Controlled Substance?  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  CLASS OF TRADE RESTRICTION:	Contact tel. # if product received damaged:  Is product returnable for credit:  Yes					
	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:						
MISCELLANEO	DUS 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:  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?