

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

Version 2024						Introduction Type:	New Item		x Final Version			Date:	8/6/2	2024
			PRODUCT INFORMAT	ION					SPECIAL HAN	IDLING AND STOR	AGE REQUIF	REMENTS*		
Company Name:	Camber Pharmac	ceuticals, Inc.				Application:	ANDA	a. Temperature	- Indicate the USP temp	erature range for th	nis product.			
Application Number for NDA/ANI	DA/BLA; PMA/510	O(k): 210203				NDA 505(b) Type:	NOT APPLICABLE		Temperature Range	Controlled Room -		and 25 C (68°	° – 77° F)	
Medical Device Class, if applicab	le:								· -					
DUNS:	11-856-3719	'							Other Temperature Range	Requirement	Excursions p	ermitted to 1	5° to 30°C (59	9° to 86°F)
Proprietary Name (If Applicable) a		ame: Capecita	abine Tablets, USP 500 mg						(write in)					
Selling Unit NDC:	31722-775-12		Unit of Use NDC:		31722-775-12		722775120		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Capecitabine Tab	olets, USP 500 mg							Is this product to be shipped				No	
								.	Is this product to be shipped	d to customers on d	ry ice?		No	
Active Ingredient(s):		Capecitabine, USP												
URL for Additional Product Inform									temperature excursion qu	estions:	Soma Raju			
Address:	prmation: www.camberpharma.com 800 Centennial Ave, Suite 1			Address 2:				Name: Number:		732-529-042	3			
City:	Piscataway				State: NJ Zip: 08854				Group E-mail:		somaraju@h		<u> </u>	
Key Contact:	Customer Service								0. oup 2a				-	
Phone Number:	1-866-827-3647								c. Special regulations for product in any states?					
Product Therapeutic Classification):	Nucleoside metabolic	inhibitor					:	Special returns requirement	ts for this product?			No	
	ADDITI	IONAL PRODUCT INFO	DRMATION			PRODUCT DESC	RIPTION INFORMATION	d. Store produc	ct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship C	Only				Protect product (unit of sa	ale) from light?		i	No	
a legend device?		No	Is the Product	Unit of Use		Size:	120 ct	e. Shelf life:		, , ,			24	Months
if yes, enter class #			Orphan Drug Status			Size:		1	Initial shelf life at launch (if different):				Months
a product kit?		No				Strength:	500 mg							
if yes, list NDCs of			FDA Approval Status							ORDER INFORM	IATION			
component parts		1.1				Dosage Form:	Biconvex, film coated tablet		Unit of Sale		What is the	NDC aalliaa		
reverse numbered? co-licensed?		No No	Allergens Present				tablet		x Bottle		1 Bottle of 12		umr	
latex-free?		Yes					Oval	-	Box/Carton			g. 1 Box of 10	(Vials)	
preservative-free?		Yes	Lactose	, Dairy		Product Shape:	014.		Ampule		(**************************************	g. 1 Box 01 10	· · · · · · · · · · · · · · · · · · ·	
correctional institution block?		No				Product Color:	Peach		Glass		Minimum or	der quantity	?	Yes
opioid?		No				Product Color:			Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint:	Debossed with '3' on one side and 'H' on the other side		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for					1 Todaot IIIIpiiliii	and 'H' on the other side		Vial Liquid Multi		If Yes, how		ch package t	type?
hospital scanning?			Is this product covered un						Vial Powder Sgl			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (TA	AA)?	No			-	Vial Powder Multi Other: Write In			Inner/Carton/ Case	Pack	
			FOR GENERIC DRUG PRO	DUOTO					Other, write in			Case		
			FOR GENERIC DRUG PRO	DUCIS										
					Διπ	horized Generic *If A	uthorized Generic, other		PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB			т	710		ion fields are not applicable	Rec. sell unit to			Rx billing ur			
II. Generic Equivalent to What Brai		Xeloda						Rec. Sell ullit to	o customer :	1	KX billing ui	Each	cy:	
ii. Generio Equivalent to What Brai		rtolodd						(Write-in, e.g. 1	1 Vial)			Gram		
		DRUG SUPPLY	CHAIN SECURITY ACT (D	SCSA) INFO	RMATION			HCPCS J-Code				Milliliter		
Does supplier meet DSCSA definit	ion of manufactur	rer?	Yes		GLN:	0331722498975			ITEN	AND PACKING IN	NFORMATION			
Is product exempt from DSCSA?			No											
If yes, select exemption:					GCP:				Weight Lbs.		ons (US msm	•	Volume	Saleable #
Other exemption - Write in:									Weight Ebs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No Yes			iginal product purchase	ed	Item/Each:	0.25	2.18	2.18	3.86	18.34	1
Is product sold by manufacturer's			No Yes	-	direct from m			Box/Carton/Bu						
Has FDA granted waiver/exception If yes, attach documentation from		roduct?	INU	1	Provide source	e manufacturer for rep	ackaged product	Inner Pack:	inale/					
ii yes, attaon accumentation from	II DA.							Case:						
		GTIN	AND HIBCC PRODUCT IN	FORMATION				June 1	6.9	13.4	9.5	5.25	668.33	24
								Pallet:						
Saleable Unit of Measure	RFID tag(Y/N)		HIBCC		GTI	N-14	Unit of Use GTIN-14							
		Quantity												
x Item/Each	N	1			0033	31722775120	00331722775120		COST INFORMATION			WHOLESALE	D LICE ON	V
Box/Carton/Bundle/Inner Pack X Case	N	24			2021	31722775124			COST INFORMATION			WHOLESALE	K USE UNL	
X Case	IN	24			2033	01122110124		Regular Cost			Vendor #:			
								Invoice Cost (V	VAC) (\$)	\$90.00	Whsl. Code	#:		
										Ţ22.00	Fineline Cod			
								As of date:	8/5/2024]	1		
								1			<u> </u>			
			Attach copy of SAFETY DAT	A SHEET (SE	S) or non hazaı		ERT, LABEL AND PHOTO OF P							
*Please provide any additional info	ermation on nage	2				See new p. 3 for Desi	gnated Drop Ship Only.	:	Signature:					



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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HA	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? Yes	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: Group 1 items (antineoplastic)						
a. UN/Identification Number	in you, indicate which						
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?							
(if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS						
a. UN/Identification Number	REINS OF REGISTRY RESTRICTIONS						
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?	1, 33516 3.1.2.						
Is the product restricted for air shipment? If so, indicate restriction:	Med Guide Required						
Passenger	Limited Distribution Requirement						
Cargo	Comments / Details: (For example, iPledge program?)						
Passenger & Cargo	Continents / Details. (For example, ir ledge program:)						
Is this a reportable quantity? No	REMS: No						
RQ Threshold: Is this a marine pollutant? Yes	REMS Program Manager Name: Phone:						
Is this a marine pollutant? Yes Is this product shipped utilizing an authorized DOT exception or Special Permit?	Supplier Manages REMS registry exclusively: 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)	ву обрыст.						
Special Permit; DOT-SP	Comments						
Special Provision (listed in Column 7 of 49 CFR 172.101);							
SP#	Registry: No						
	Registry Program Contact Name: Phone:						
ADD'L STORAGE INFORMATION	Registry Program Contact Name. Comments						
	Continuents						
Is the Product	DETURN INSTRUCTIONS						
Controlled Substance? No Controlled Substance Code	RETURN INSTRUCTIONS						
Controlled by State(s)? No Listed Chemical (List I or II) No APOCO Reportable 2	4.000.007.0047						
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: Yes						
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						
Restricted to hospital, clinics, and physician offices only: No	, NO						
Restricted from US territories? (explain in comments) No	If so, which states? Other requirements? Comments?						
Comments:							
MISCELLANE	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: 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?						