

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

Version 2024						Introduction Type:	New Item		x Final Version			Date:	2/27/	/2025
			PRODUCT INFORMAT	TION					SPECIAL HAN	IDLING AND STOR	AGE REQUI	REMENTS*		
Company Name:	Camber Pharmace	euticals, Inc.				Application:	ANDA	a. Temperatur	e – Indicate the USP temp	erature range for t	his product.			
Application Number for NDA/ANI	DA/BLA; PMA/510(k): 209438				NDA 505(b) Type:	NOT APPLICABLE		Temperature Range	Controlled Room -		and 25 C (68	° – 77° F)	
Medical Device Class, if applicab	ole:							[
DUNS:	11-856-3719								Other Temperature Range	Requirement				
Proprietary Name (If Applicable) and		me: Oseltarr	nivir Phosphate Capsules, L	JSP 30 mg (base)				(write in)					
Selling Unit NDC:	31722-630-31		Unit of Use NDC:				22630313		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Oseltamivir Phosp	hate Capsules, USP 3	0 mg (base)						Is this product to be shippe	d to customers on id	ce?		No	
									Is this product to be shippe	d to customers on d	Iry ice?		No	
Active Ingredient(s):		Oseltamivir phosphar	ie, USP											
UDI for Additional Deaduct Inform	atlan	www.camberpharma.						b. Contact for	temperature excursion que Name:	estions:	Soma Raju			
URL for Additional Product Inform Address:	800 Centennial Av					Address 2:			Number:		732-529-042	2		
City:	Piscataway	o, outo i			State:	NJ Zin	08854		Group E-mail:			eterousa.cor	n	
Key Contact:	Customer Service				Email:		customerservice@camberpharma.com							
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special reg	ulations for product in any	states?			No	1
Product Therapeutic Classification	n:	Influenza neuraminid	ase inhibitor (NAI)						Special returns requiremen	ts for this product?			No	
														_
	ADDITIC	ONAL PRODUCT INF	ORMATION			PRODUCT DESC	RIPTION INFORMATION	d. Store produ	uct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship On	ly				Protect product (unit of s	ale) from light?			No	1
a legend device?		No	Is the Product	Unit Dose		Size:	10 unit dose capsules	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status			0120.			Initial shelf life at launch	if different):				Months
a product kit?		No				Strength:	30 mg							
if yes, list NDCs of component parts			FDA Approval Status				Hard gelatin capsule			ORDER INFORM	TATION			
reverse numbered?		No				Dosage Form:	Hard gelatin capsule		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						Bottle		1 Carton of			
latex-free?		Yes				Barris Alexandre	Capsule		x Box/Carton			g. 1 Box of 1		
preservative-free?		Yes	Alconol,	, Lactose		Product Shape:			Ampule					
correctional institution block?		No				Product Color:	Light yellow opaque cap and light yellow opaque body		Glass		Minimum or	der quantity	?	Yes
opioid?		No							Tube					
Cannabinoid?	- 11 - 4	No	Country of Origin	India		Product Imprint:	Imprinted with 'H' on cap and '33' on body with blue ink		Vial Liquid Sgl		W. V			
If Unit Dose, is item bar coded to un hospital scanning?	nit dose for	Yes	Is this product covered ur	nder the					Vial Liquid Multi Vial Powder Sgl			Each	ch package t	type?
If Unit Dose, indicate NDC here:		31722-630-31	Trade Agreements Act (T		No				Vial Powder Multi		155	Inner/Cartor	Pack	
			1	, L					Other: Write In			Case		
			FOR GENERIC DRUG PRO	ODUCTS								4		
					Au		uthorized Generic, other		Pl	IARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB					sect	on fields are not applicable	Rec. sell unit	to customer?		Rx billing u	nit to pharm	acy:	
II. Generic Equivalent to What Bran	nd?:	Tamiflu										Each		
								(Write-in, e.g.				Gram		
		DRUG SUPPLY	CHAIN SECURITY ACT (I	DSCSA) INFORM	ATION			HCPCS J-Cod	e:			Milliliter		
Does supplier meet DSCSA definit	ion of manufactur	or2	Yes		GLN:	0331722498975			ITE	AND PACKING IN		N		
Is product exempt from DSCSA?			No	-	OLIN.	0001122400010						•		
If yes, select exemption:														Saleable #
II YES, SEICULEXEIIIDUUUI.					GCP-					Dimonei	ons (US men	nts)	Volume	Pieces
					GCP:				Weight Lbs.		ons (US msn Width		Volume (Cube)	
Other exemption - Write in: Is product repackaged?			No			riginal product purchase	d	Item/Each:	-	Depth	Width	Height	(Cube)	
Other exemption - Write in:	exclusive distribu	tor?	Yes				d	Item/Each:	Weight Lbs.					1
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptior	n/exemption for pro				If yes, was or direct from m			Box/Carton/B	0.06	Depth	Width	Height	(Cube)	1
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	n/exemption for pro		Yes		If yes, was or direct from m	nfr?		Box/Carton/Bo Inner Pack:	0.06	Depth	Width	Height	(Cube)	1
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptior	n/exemption for pro	oduct?	Yes No		If yes, was or direct from m	nfr?		Box/Carton/B	0.06	Depth	Width	Height	(Cube)	1
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptior	n/exemption for pro	oduct?	Yes		If yes, was or direct from m	nfr?		Box/Carton/B Inner Pack: Case:	0.06	Depth 5	0.75	Height 3.8	(Cube)	
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptior If yes, attach documentation from	n/exemption for pro	oduct?	Yes No AND HIBCC PRODUCT IN		If yes, was or direct from m Provide sour	nfr? ce manufacturer for rep	ackaged product	Box/Carton/Bo Inner Pack:	0.06	Depth 5	0.75	Height 3.8	(Cube)	
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptior	n/exemption for pro	oduct?	Yes No		If yes, was or direct from m Provide sour	nfr?		Box/Carton/B Inner Pack: Case:	0.06	Depth 5	0.75	Height 3.8	(Cube)	
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptior If yes, attach documentation from	n/exemption for pro	oduct? GTIN Saleable	Yes No AND HIBCC PRODUCT IN		If yes, was or direct from m Provide sour Provide sour	nfr? ce manufacturer for rep	ackaged product	Box/Carton/B Inner Pack: Case:	0.06 undle/ 9.7	Depth 5	Width 0.75 13.25	Height 3.8 12	(Cube) 14 2504	135
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Carton/Bundle/Inner Pack	v/exemption for pro n FDA. RFID tag(Y/N)	GTIN Saleable Quantity 1	Yes No AND HIBCC PRODUCT IN		If yes, was or direct from m Provide sour GTI 003	nfr? ce manufacturer for rep: N-14 31722630313	ackaged product	Box/Carton/B Inner Pack: Case:	0.06	Depth 5	Width 0.75 13.25	Height 3.8 12	(Cube)	135
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Cattor/Bundle/Inner Pack X Case	n/exemption for pron n FDA. RFID tag(Y/N)	oduct? GTIN Saleable	Yes No AND HIBCC PRODUCT IN		If yes, was or direct from m Provide sour GTI 003	nfr? ce manufacturer for rep: N-14	ackaged product	Box/Carton/Bo Inner Pack: Case: Pallet:	0.06 undle/ 9.7	Depth 5	Width 0.75 13.25	Height 3.8 12	(Cube) 14 2504	135
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Carton/Bundle/Inner Pack	v/exemption for pro n FDA. RFID tag(Y/N)	GTIN Saleable Quantity 1	Yes No AND HIBCC PRODUCT IN		If yes, was or direct from m Provide sour GTI 003	nfr? ce manufacturer for rep: N-14 31722630313	ackaged product	Box/Carton/Bi Inner Pack: Case: Pallet: Regular Cost	COST INFORMATION	Depth 5 15.75	Vidth 0.75 13.25 Vendor #:	Height 3.8 12 WHOLESAL	(Cube) 14 2504	135
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Cattor/Bundle/Inner Pack X Case	v/exemption for pro n FDA. RFID tag(Y/N)	GTIN Saleable Quantity 1	Yes No AND HIBCC PRODUCT IN		If yes, was or direct from m Provide sour GTI 003	nfr? ce manufacturer for rep: N-14 31722630313	ackaged product	Box/Carton/Bo Inner Pack: Case: Pallet:	COST INFORMATION	Depth 5 15.75	Vidth 0.75 13.25 Vendor #: Whsl. Code	Height 3.8 12 WHOLESAL #:	(Cube) 14 2504	135
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Cattor/Bundle/Inner Pack X Case	v/exemption for pro n FDA. RFID tag(Y/N)	GTIN Saleable Quantity 1	Yes No AND HIBCC PRODUCT IN		If yes, was or direct from m Provide sour GTI 003	nfr? ce manufacturer for rep: N-14 31722630313	ackaged product	Box/Carton/B Inner Pack: Case: Pallet: Regular Cost Invoice Cost (0.06 undle/ 9.7 COST INFORMATION WAC) (\$)	Depth 5 15.75	Vidth 0.75 13.25 Vendor #:	Height 3.8 12 WHOLESAL #:	(Cube) 14 2504	135
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Cattor/Bundle/Inner Pack X Case	v/exemption for pro n FDA. RFID tag(Y/N)	GTIN Saleable Quantity 1	Yes No AND HIBCC PRODUCT IN		If yes, was or direct from m Provide sour GTI 003	nfr? ce manufacturer for rep: N-14 31722630313	ackaged product	Box/Carton/Bi Inner Pack: Case: Pallet: Regular Cost	COST INFORMATION	Depth 5 15.75	Vidth 0.75 13.25 Vendor #: Whsl. Code	Height 3.8 12 WHOLESAL #:	(Cube) 14 2504	135
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Cattor/Bundle/Inner Pack X Case	v/exemption for pro n FDA. RFID tag(Y/N)	GTIN Saleable Quantity 1	Yes No AND HIBCC PRODUCT IN		If yes, was or direct from m Provide sour GTI 003	nfr? ce manufacturer for rep: N-14 31722630313	ackaged product	Box/Carton/B Inner Pack: Case: Pallet: Regular Cost Invoice Cost (0.06 undle/ 9.7 COST INFORMATION WAC) (\$)	Depth 5 15.75	Vidth 0.75 13.25 Vendor #: Whsl. Code	Height 3.8 12 WHOLESAL #:	(Cube) 14 2504	135
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Catror/Bundle/Inner Pack X Case	v/exemption for pro n FDA. RFID tag(Y/N)	GTIN Saleable Quantity 1 135	Yes No AND HIBCC PRODUCT IN HIBCC	NFORMATION	f yes, was or direct from m Provide sour GTI 003 303	N-14 31722630313 31722630314	ackaged product	Box/Carton/B Inner Pack: Case: Pallet: Regular Cost Invoice Cost (As of date:	COST INFORMATION WAC) (\$) 8/1/2020	Depth 5 15.75	Vidth 0.75 13.25 Vendor #: Whsl. Code	Height 3.8 12 WHOLESAL #:	(Cube) 14 2504	135
Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Catror/Bundle/Inner Pack X Case	Vexemption for pro	GTIN Saleable Quantity 135	Yes No AND HIBCC PRODUCT IN HIBCC	NFORMATION	f yes, was or direct from m Provide sour GTI 003 303	hr? ce manufacturer for repr N-14 31722630313 31722630314 intractional statements intractional statements intractional statements	Unit of Use GTIN-14	Box/Carton/B Inner Pack: Case: Pallet: Regular Cost Invoice Cost (As of date:	COST INFORMATION WAC) (\$) 8/1/2020	Depth 5 15.75	Vidth 0.75 13.25 Vendor #: Whsl. Code	Height 3.8 12 WHOLESAL #:	(Cube) 14 2504	135

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

Version 2024 For Designa	ted Drop Ship Only Products, Please Use Page 3
MATERIAL HA	ZARD CLASSIFICATION and TRANSPORTATION
Is this product (check all that apply): a. Cytotoxic? No 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? 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? No	x Organic Corrosive Inorganic Oxidizer Steroid/Androgen Contact Hazard Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No NFPA Storage Level: Image: Contact Hazard
(if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Is the product a NIOSH hazardous drug? If yes, indicate which: Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics
Is this product regulated for shipment by IATA? No (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	REMS or REGISTRY RESTRICTIONS Is there a REMS on this product? No If Yes, is it managed with a pharmacy registry? No Website URL: Image: Colored and Col
Is the product restricted for air shipment? If so, indicate restriction: Passenger No Cargo Passenger & Cargo Is this a reactable quantity? No	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?) REMS: No
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) Special Permit; DOT-SP Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);	REMS: No REMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively: Phone: Wholesale distributor support: Provider Name: Site Enrollment Number assigned DEA #: by Supplier: NPI #:
SP#	Registry: No Registry Program Contact Name: Phone:
ADD'L STORAGE INFORMATION Is the Product Controlled Substance Code	Comments RETURN INSTRUCTIONS
Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) No ARCOS Reportable? No If yes, indicate which: No Schedule No. Is it a scheduled listed chemical product?: No	KEI URN INSTRUCTIONS Contact tel. # if product received damaged: 1-866-827-3647 Is product returnable for credit: Yes URL/Link to returns policy: Yes
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 Restricted to hospital, clinics, and physician offices only: No Restricted from US territories? (explain in comments) No	Special regulations or returns requirements for this product in certain states? No If so, which states? Other requirements? Comments?
MISCELLANE	OUS NOTES and/or Image of Product Barcode:



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Version 2024	FOR DESIGNATED DROP SHIP PRODUCT ONLY - if r	ot a designated drop ship, do not complete.				
Order Method for Des	signated 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 Expedited Freight Charges o		Purchase order daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Hours Da Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt: Overnight and Priority Overnight PO Processing	ays			
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:		Days of week overnight is available: Monday				
Comments:	s only:	Days of week overnight is available: Tuesday Tuesday Wednessi Priority Overnight receipt available: Friday PO Receipt Cut off time: PO Receipt Cut off time: Order receipt method: Phone: Fax: EDI: Overnight Fees apply: Policity	/ day			
Other Data Informati	ion Required to Process PO:	Return Instructions				
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # 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?				
Miscell	aneous Notes:					
		ADDITIONAL INFORMATION				
		Is product order for scheduled patient procedure? Is product order for restocking purposes?				