

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

					Introduction Type:	New Item	X	Final Version			Date:	2/2//	2025
		PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	AGE REQUI	REMENTS*		
	armaceuticals, Inc.				Application:	ANDA	a. Temperature – Indic	ate the USP tempe					
Application Number for NDA/ANDA/BLA; PI	IA/510(k): 20943	38			NDA 505(b) Type:	NOT APPLICABLE		ature Range	Controlled Room -		and 25 C (68	° – 77° F)	
Medical Device Class, if applicable:													
DUNS: 11-856-37								mperature Range F	Requirement				
Proprietary Name (If Applicable) and Establis		amivir Phosphate Capsules,)				ite in)					
Selling Unit NDC: 31722-632	31	Unit of Use NDC:			UPC: 33172 MVX Code:	22632317	Notes						
· ·		CVX Code:			MYA Code.		1						
Description: Oseltamiv	Phosphate Capsules, USF	P 75 mg (base)						oduct to be shipped				No	
Active Ingredient(s):	Oseltamivir phospl	hata IISD					is this pr	oduct to be shipped	to customers on a	y ice?		No	
Active ingredient(s).	Oseitainivii priospi	nate, ooi					b. Contact for tempera	ture excursion au	estions:				
URL for Additional Product Information:	www.camberpharm	na.com					Name:			Soma Raju			
Address: 800 Cente	nial Ave, Suite 1				Address 2:		Number	:		732-529-042			
City: Piscatawa				State:		08854	Group E	-mail:		somaraju@h	eterousa.con	<u>1</u>	
Key Contact: Customer Phone Number: 1-866-827				Email: Fax:	customerservice@camb	<u>erpharma.com</u>	- Cunsial resculations	fan muadwat in am.				No	
		nidase inhibitor (NAI)		rax:	/32-562-8/88		c. Special regulations						
Product Therapeutic Classification:	innuenza neuramir	lidase inhibitor (NAI)					Special i	returns requirement	s for this product?			No	
	DDITIONAL PRODUCT IN	JEORMATION			PRODUCT DESCR	IPTION INFORMATION	d. Store product (unit of	of sale) unright?				No	
The product is?		Is the Product	Direct-Ship On	ls.	1 1105001 52001		- 1	product (unit of sa	la) fram limbt?			No	
a legend device?	No	Is the Product	Unit Dose	ıy		10 unit dose capsules	e. Shelf life:	product (unit or sa	ie) from light?			24	Months
if yes, enter class #	INU	Orphan Drug Status	2.111. 2.000		Size:	. o at dooc capoulos		nelf life at launch (i	f different):			2-7	Months
a product kit?	No				Strongth	75 mg		,	•				
if yes, list NDCs of		FDA Approval Status			Strength:				ORDER INFORM	ATION			
component parts					Dosage Form:	Hard gelatin capsule							
reverse numbered? co-licensed?	No No	Allergens Present					Unit of S	Sale Bottle		What is the	0 Unit Dose		
latex-free?	Yes	J				Capsule	x	Box/Carton			g. 1 Box of 10		
preservative-free?	Yes	Alcohol	l, Lactose		Product Shape:	Capsuic		Ampule		(vviite iii, e.	g. 1 DOX 01 10	, viais,	
correctional institution block?	No				Product Color:	Light yellow opaque cap		Glass		Minimum or	der quantity	?	Yes
opioid?	No				Product Color:	and grey opaque body		Tube					
Cannabinoid?	No	Country of Origin	India		Product Imprint:	Imprinted with 'H' on cap and '5' on body with blue ink		Vial Liquid Sgl					
If Unit Dose, is item bar coded to unit dose for	N.					OT DOGY WILLT DIGE ITIK		Vial Liquid Multi		If Yes, how		ch package	ype?
hospital scanning? If Unit Dose, indicate NDC here:	Yes 31722-632-31	Is this product covered u Trade Agreements Act (No				Vial Powder Sgl Vial Powder Multi		135	Each Inner/Carton	/Dack	
ii oint bose, indicate NBO nere.	01722 002 01	Trade rigidements rice (10				Other: Write In			Case	ii dok	
		FOR GENERIC DRUG PR	ODUCTS		<u>, </u>								
				Δ.,	thorized Generic *If Au	thorized Generic, other		PH	ARMACY ORDER	BILL UNIT			
			L	Au									
I. Orange Book Rating: AB				Au		n fields are not applicable	Rec. sell unit to custon	ner?		Rx billing u	nit to pharma	ıcy.	
I. Orange Book Rating: II. Generic Equivalent to What Brand?:	Tamiflu			Au		on fields are not applicable		ner?		Rx billing u	Each	icy.	
		I V CHAIN SECUDITY ACT	(DSCSA) INFORM			n fields are not applicable	(Write-in, e.g. 1 Vial)	mer?		Rx billing u	Each Gram	icy.	
		LY CHAIN SECURITY ACT ((DSCSA) INFORM			n fields are not applicable		mer?]	Rx billing u	Each	icy.	
II. Generic Equivalent to What Brand?:	DRUG SUPP			MATION	section	n fields are not applicable	(Write-in, e.g. 1 Vial)]		Each Gram Milliliter	icy.	
	DRUG SUPP	LY CHAIN SECURITY ACT (Yes No				n fields are not applicable	(Write-in, e.g. 1 Vial)		AND PACKING IN		Each Gram Milliliter	icy.	
II. Generic Equivalent to What Brand?: Does supplier meet DSCSA definition of man is product exempt from DSCSA?	DRUG SUPP	Yes		MATION GLN:	section	n fields are not applicable	(Write-in, e.g. 1 Vial)	ITEM	AND PACKING IN	FORMATION	Each Gram Milliliter		Saleable #
II. Generic Equivalent to What Brand?: Does supplier meet DSCSA definition of man	DRUG SUPP	Yes		MATION	section	n fields are not applicable	(Write-in, e.g. 1 Vial)		AND PACKING IN		Each Gram Milliliter	Volume (Cube)	Saleable #
II. Generic Equivalent to What Brand?: Does supplier meet DSCSA definition of man is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	DRUG SUPP	Yes No		MATION GLN: GCP: f yes, was or	section sec		(Write-in, e.g. 1 Vial)	ITEM Weight Lbs.	AND PACKING IN Dimension	FORMATION ons (US msm Width	Each Gram Milliliter	Volume (Cube)	Pieces
II. Generic Equivalent to What Brand?: Does supplier meet DSCSA definition of man Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's exclusive	DRUG SUPP	Yes No No Yes		IATION GLN: GCP: f yes, was or direct from m	0331722498975 iginal product purchased		(Write-in, e.g. 1 Vial) HCPCS J-Code:	ITEM	AND PACKING IN	FORMATION	Each Gram Milliliter	Volume	
II. Generic Equivalent to What Brand?: Does supplier meet DSCSA definition of man Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's exclusive Has FDA granted waiver/exception/exemption.	DRUG SUPP	Yes No		IATION GLN: GCP: f yes, was or direct from m	section sec		(Write-in, e.g. 1 Vial) HCPCS J-Code: Item/Each: Box/Carton/Bundle/	ITEM Weight Lbs.	AND PACKING IN Dimension	FORMATION ons (US msm Width	Each Gram Milliliter	Volume (Cube)	Pieces
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II. Generic Equivalent to What Brand?: Does supplier meet DSCSA definition of man Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's exclusive Has FDA granted waiver/exception/exemptio If yes, attach documentation from FDA. Saleable Unit of Measure RFID tag X Item/Each N Bow/Carton/Bundle/Inner Pack	DRUG SUPP ifacturer? istributor? for product? GT (Y/N) Saleable Quantity 1	Yes No No Yes No IN AND HIBCC PRODUCT I		GLN: GCP: f yes, was or direct from m Provide source GTII	section sectin section section section section section section section section	ckaged product	(Write-in, e.g. 1 Vial) HCPCS J-Code: Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet:	Weight Lbs.	AND PACKING IN Dimension Depth	FORMATION ons (US msm Width 0.75	Each Gram Milliliter tts.) Height 3.8	Volume (Cube) 14	1 135
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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? No Does the product label bear a CA Prop 65 warning? No	x Organic Corrosive Inorganic 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?	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:					
c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Hazardous Waste Identification					
ls this product regulated for shipment by IATA?	EPA Hazardous Waste Code: Waste Characteristics					
(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: DEA #: NCPDP#: NCPDP#: NPI #:					
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments Registry: No					
	Registry Program Contact Name: Phone:					
ADD'L STORAGE INFORMATION	Comments					
Is the Product Controlled Substance? Controlled Substance Code 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	RETURN INSTRUCTIONS Contact tel. # if product received damaged: 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: 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? If so, which states? Other requirements? Comments?					
Comments:						
MISCELLAN	EOUS NOTES and/or Image of Product Barcode:					



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

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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	Purchase order daily receipt cut off time by supplier Cut off time:
b. Autofax 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
Class of Trade Restriction:	Priority Overnight receipt available: 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: 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?