

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014					Introduction	i Type:	New Item		Final Version			Date:	3/8/	/2018
			PRODUCT INFORMATION						SPECIAL HANDL	ING AND STO	DRAGE REQ	JIREMENTS*	*	
Company Name:	Camber Pharmaceuti	rals			A	oplication:	ANDA	a. Temperature – Indica	ate the USP temper	aturo ranno f	or this produ	ıct		
Application Number for ND):	209438		,			ure Range	atare range i			en 20 and 25	C (68° – 77° F
DUNS:	82-667-4775		<u>, </u>					-	mperature Range Re					,
Proprietary Name (If Applical		Name: Osoltami	vir Phosphate 30MG 10CT						te in)	quirement				1
Selling Unit NDC:	31722-630-31	dille.	Individual Unit NDC:		UPC	3317226303	313	1	ic iii)					1
UDI			CVX Code:		MVX Code:			Is this pro	duct to be shipped to	o customers o	n ice?		No	
Description:	Light vollow opague o	an/Light vollow opague b	ody size '4' hard gelatin capsules	imprinted with 'H' on can		with blue ink fille	ad with white to off white	= 1	oduct to be shipped to				No	-
Description.	granular powder.	apreignt yellow opaque b	ody 3126 4 Hard gelatiii capsules	implifica with 11 on cap	Jana 55 on body	with blue line, file	od with white to on white	lis tills pro	radet to be shipped to	o customers c	in dry loc:		110	_
Active Ingredient(s):	·	Oseltamivir phosphate						b. Contact for tempera	ture excursion que	stions:				
								Name:			Soma Raju			
URL for Additional Product I					Address O			Number:			732-529-0423 somaraju@heterousa.com			
Address:	1031 Centennial Ave	nue		State	Address 2:	71	00054	Group E-	-mail:		somaraju@h	eterousa.cor	n	
City: Key Contact:				NJ	Zip:	08854	c. Special regulations f	or product in any o	totoo?			No		
Phone Number:	732-529-0430				Fax: 732-562-8788				eturns requirements f		t?		No	-
Product Therapeutic Classifi														-
								d. Store product (unit of	of sale) upright?				No	
ADDITIONA	AL PRODUCT INFORM	ATION	1	F	PRODUCT DESCR	RIPTION INFORM	MATION		product (unit of sale	e) from light?			No	-
Is the Product								e. Shelf life:	•	-			24	Months
a legend device?		No							elf life at launch (if c	different):				Months
reverse numbered?		No		Size:	1x10 bli	ster pack			·	•		1		
co-licensed?		No		Strength:	30MG				C	ORDER INFO	RMATION			
Is the Product		Direct-Ship Only												
Is the Product		Unit Dose		Dosage Form:	: capsule			Unit of S	ale Bottle		1 blister pac	NDC selling	unit?	
								x	Box/Carton			g. 1 Box of 1	0 Vials)	
If Unit Dose, is item bar code	ed to unit dose for hosp	ital scanning?							Ampule		(**************************************	g Dox o	o viaio,	
If Unit Dose NDC, indicate NI	DC here:			Product Shape	n/a				Glass		Minimum o	der quantity	<i>i</i> ?	Yes
				Product Color:	r Light ve	llow opaque			Tube					
Country of Origin		India		1 Todaet Gold.	Light yo	non opaquo			Vial Liquid Sgl					
Is this product covered under	r the Trade Agreements	Act (TAA)?		Product Imprir	nt: H/33				Vial Liquid Multi Vial Powder Sql		If Yes, how	many of whi	ch package	type?
									Vial Powder Sqi Vial Power Multi		1	Inner/Carton	/Pack	
L														
			1					'l - 	Other: Write In			Case		
			FOR GENERIC DRUG PRODU	стѕ				4		7				
			FOR GENERIC DRUG PRODU					<u>-</u>	Other: Write In			Case		
			FOR GENERIC DRUG PRODU		orized Generic		d Generic, other section		Other: Write In	RMACY ORDE		Case		
I. Orange Book Rating:	AB		FOR GENERIC DRUG PRODU		orized Generic	*If Authorized		Rec. sell unit to custon	Other: Write In	RMACY ORDE	R / BILL UNI	Case T nit to pharma	асу:	
I. Orange Book Rating:		Tamiflu	FOR GENERIC DRUG PRODU		orized Generic			Rec. sell unit to custon	Other: Write In	RMACY ORDE	R / BILL UNI	Case T nit to pharma Each	асу:	
				Autho	orized Generic				Other: Write In	RMACY ORDE	R / BILL UNI	Case T nit to pharma Each Gram	асу:	
			FOR GENERIC DRUG PRODU	Autho	orized Generic			Rec. sell unit to custon	Other: Write In	RMACY ORDE	R / BILL UNI	Case T nit to pharma Each	асу:	
	at Brand?:	DRUG SUPPI		Autho	orized Generic			Rec. sell unit to custon	Other: Write In PHAR	RMACY ORDE	R / BILL UNI	Tinit to pharma Each Gram Milliliter	acy:	
II. Generic Equivalent to Who	at Brand?: definition of manufac	DRUG SUPP	LY CHAIN SECURITY ACT (DSC	Autho	orized Generic			Rec. sell unit to custon	Other: Write In PHAR	ND PACKING	R / BILL UNI	T nit to pharma Each Gram Milliliter		
II. Generic Equivalent to Who	at Brand?: definition of manufac CSA?	DRUG SUPP	LY CHAIN SECURITY ACT (DSC Yes	Autho	orized Generic			Rec. sell unit to custon	Other: Write In PHAR ner? ITEM A	ND PACKING	R / BILL UNI Rx billing uni INFORMATI	T mit to pharma Each Gram Milliliter ON	Volume	# Pieces:
II. Generic Equivalent to Who Does supplier meet DSCSA Is product exempt from DSC If yes, select exemption: Other exemption - Write in:	at Brand?: definition of manufac CSA?	DRUG SUPP	LY CHAIN SECURITY ACT (DSC Yes No	Autho SA) INFORMATION GLN:		fields are not		Rec. sell unit to custon (Write-in, e.g. 1 Vial)	Other: Write In PHAR	ND PACKING	R / BILL UNI	T nit to pharma Each Gram Milliliter		# Pieces:
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Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL H	HAZARD CLASSIFICATION and TRANSPORTATION	
Is this product (check all that apply):		,
a. Cytotoxic?	SDS Hazard Classification	
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	ODO HAZARA GRADANIONI	
Is the product a CA Prop 65 carcinogen?	Organic Corrosive	
Is the product a CA Prop 65 carcinogen?	Inorganic Oxidizer	
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard	
- O-st-st-H10	Associated Characteristic NETPA Characteristics	
c. Contact Hazard?	Aerosol Class; Identify NFPA Storage Level:	
d. Does this product require special clean-up instructions? No		
(If yes, attach SDS with special instructions.)	Is the product a NIOSH hazardous drug?	
e. Does the product contain DEHP? No	If yes, indicate which:	
Is this product regulated for shipment by DOT or IATA?		
(if yes, answer a-e below and provide SDS)		
a. UN/Identification Number		
b. Proper Shipping Name	Hazardous Waste Identification	
c. DOT Hazard Class	EPA Hazardous Waste Code:	
d. Packing Group		
e. Inhalation Hazard?		
	DELIA DEGLETA DESTRUCTIONA	
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS	
Passenger	Is there a REMS on this product?	
Cargo	If Yes, is it managed with a pharmacy registry?	
Passenger & Cargo	Website URL:	
Is this a reportable quantity? No		
RQ Threshold:	Comments / Details: (For example, iPledge program?)	
Is this a marine pollutant?		
Is this product shipped utilizing an authorized DOT exception or Special Permit?		
No (if yes, identify method below)	REMS:	
Limited Quantity	REMS Program Manager Name: Phone:	
Consumer Commodity, ORM-D	Supplier Manages REMS registry exclusively: No	
Small Quantity (49 CFR 173.4)	Wholesale distributor support: No	
Special Permit; DOT-SP	Provider Name:	
Special Provision (listed in Column 7 of 49 CFR 172.101);	Site Enrollment Number assigned DEA #: No	
SP#	by Supplier: PCPDP #: No	
01 #		
ADD'L STORAGE INFORMATION	NPI #: No	
Is the Product	Comments	
	Comments	
	Pariety, No.	
Controlled by State(s)? ARCOS Reportable? No	Registry: No	
·	Registry Program Contact Name: Phone:	
Schedule No. (inc. N for non-narcotic)	Comments	
Controlled Substance Code	RETURN INSTRUCTIONS	
Listed Chemical (List I or II) No	RETURN INSTRUCTIONS	
If yes, indicate which:		
Is it a scheduled listed chemical product?: No	Contact tel. # if product received damaged: 732-529-0430	
CLASS OF TRADE RESTRICTION:	Is product returnable for credit:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	URL/Link to returns policy: contact - customerservice@camberpharma.com	
Restricted to retail pharmacy only: Yes	Special regulations or returns requirements for this product in certain states?	
Restricted to hospital, clinics, and physician offices only:	If so, which states? Other requirements? Comments?	
Restricted from US territories? (explain in comments) No		
Comments:		
Comments.		
MISCELLAN	NEOUS NOTES and/or Image of Product Barcode:	



Standard Pharmaceutical Product Information (Page 3)

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 Yes No Fax Number:	Purchase order daily receipt cut off time by supplier Cut off time: 2:30PM Eastern				
c. Fax d. Phone only No Phone No.:	Shipping lead time of PO: 24/48 Hours Days				
e. Supplier Web Site only No Site Address:	Ships same day for next day receipt: No				
Minimum Order Quantity: case pack	Ships for second day receipt: No				
Supplier's Customer Service Number: 732-529-0430 x466 x465 x467 x470	Ships regular ground for 3-10 days receipt: Yes				
Contracted 3PL company / contact #: Name: Phone:					
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing				
Expedited freight fees billed with each order: No No	Overnight receipt available: Yes				
Drop Ship service fee billed with each order: No No	PO Receipt cut off time: 2:30PM Eastern				
Drop Ship miscellaneous fees billed: No	Days of week overnight is available:				
Comments:	x Tuesday x Wednesday Thursday x Friday				
	Priority Overnight receipt available: Yes				
Class of Trade Restriction:	PO Receipt Cut off time: 2:30PM EST				
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices No	Saturday Overnight receipt available: No				
Restricted to retail pharmacy only: Yes	PO Receipt Cut off time:				
Restricted to hospital, clinics, and physician offices only: No	Order receipt method: No Phone #:				
Restricted from US territories? (explain in comments) No	Fax: Yes Fax #: 732-562-8788				
Comments:	EDI: Yes				
	Overnight Fees apply: Other fees apply: No				
Other Data Information Demoired to Decree DO					
Other Data Information Required to Process PO:	Return Instructions				
Patient Procedure Date: Physician Name:	Contact # if product is received damaged: Is product returnable for credit: Yes				
Physician/Clinic Phone #	URL/Link to returns policy:				
Physician State License #	Special regulations or returns requirements for this product in certain states? Yes				
Physician/Clinic DEA #:	If so, which states? Other requirements? Comments?				
Physician/Clinic Specialty:	·				
Miscellaneous Notes:					
	ADDITIONAL INFORMATION				
	Is product order for scheduled patient procedure?				
	Is product order for restocking purposes?				