

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014					Introduction Type:	Post Launch Change	01	Final Version			Date:	10/16	/2020
			PRODUCT INFORMAT	ION				SPECIAL HANDL	LING AND STO	RAGE REQ	UIREMENTS	*	
Company Name:	Camber Pharmaceutic	cals			Applicatio	on: ANDA	a. Temperature – Inc	dicate the USP temper	rature range f	or this produ	ct.		
Application Number for ND			e):	202438		'		erature Range				en 20 and 25	C (68° – 77°
DUNS:	82-667-4775						Other	Temperature Range Re	equirement				
Proprietary Name (If Applical		Name: Famcic	ovir Tablets 125MG 30CT					(write in)	equirement				
Selling Unit NDC:	31722-706-30		Individual Unit NDC:	31722-706-3	0 UPC: 3317	22706308							
UDI	NA	•	CVX Code:		MVX Code: NA		Is this	product to be shipped	to customers of	n ice?		No	
Description:	White, capsule shape	d tablets, imprinted with	'50' on upper and 'I' on lower		_		Is this	product to be shipped	to customers of	n dry ice?	•	No	
		, ,								,			
Active Ingredient(s):		Famciclovir					b. Contact for temper	erature excursion que	stions:				
							Name			Soma Raju			
URL for Additional Product II		www.camberpharma.co	om	1			Numb			732-529-042			
Address: City:	1031 Centennial Aver Piscataway	nue		State:	Address 2:	08854	Group E-mail:			somaraju@heterousa.com			
Key Contact:	Customer Service			Email:	customerservice@cambo		a Special regulations for product in any states?						
Phone Number:	732-529-0430			Fax:	732-562-8788	огрлагна.оот		c. Special regulations for product in any states? Special returns requirements for this product? No					
Product Therapeutic Classifi											•		
							d. Store product (un	it of sale) upright?				No	
ADDITIONA	AL PRODUCT INFORM	ATION			PRODUCT DESCRIPTION	INFORMATION		ct product (unit of sale	e) from light?			Yes	
Is the Product							e. Shelf life:					24	Months
a legend device?		No		Size:	30			shelf life at launch (if	different):				Months
reverse numbered?		No		Size.	30								
co-licensed?		No		Strength:	125 mg			(ORDER INFOR	RMATION			
Is the Product		Direct-Ship Only Unit of Use			- 9			£0-1-		14/h-4 :- 4h-	NDC selling		
is the Product		Unit of Use		Dosage Fore	n: tablet		Unit o	of Sale Bottle		1 box of 48		unit?	
							-				g. 1 Box of 1	0 Vials)	
If Unit Dose, is item bar code	ed to unit dose for hospi	ital scanning?		Donato et Obe			1 	Ampule		(g	,	
If Unit Dose NDC, indicate NI	DC here:			Product Sha	capsule shaped			Glass		Minimum o	rder quantity	?	Yes
				Product Col	or: White			Tube					
Country of Origin		India		Froduct cor	or.			Vial Liquid Sgl		W.V 1		-t t 4	
Country of Origin Is this product covered under		Act (TAA)?		Product Imp				Vial Liquid Multi		If Yes, how		ch package t	ype?
, ,]					Vial Liquid Multi Vial Powder Sql			Each		ype?
, ,		Act (TAA)?]					Vial Liquid Multi		If Yes, how			ype?
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Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION Is this product (check all that apply): SDS Hazard Classification a. Cvtotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? 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 Aerosol Class; Identify NFPA Storage Level: c. Contact Hazard? No 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? No (if yes, answer a-e below and provide SDS) a. UN/Identification Number Hazardous Waste Identification b. Proper Shipping Name c. DOT Hazard Class EPA Hazardous Waste Code: d. Packing Group e. Inhalation Hazard? Yes REMS or REGISTRY RESTRICTIONS Is the product restricted for air shipment? If so, indicate restriction: Passenger Is there a REMS on this product? No Cargo If Yes, is it managed with a pharmacy registry? Passenger & Cargo Website URL: Is this a reportable quantity? No Comments / Details: (For example, iPledge program?) RQ Threshold: Is this a marine pollutant? No Is this product shipped utilizing an authorized DOT exception or Special Permit? (if yes, identify method below) REMS: Limited Quantity REMS Program Manager Name: Phone Consumer Commodity, ORM-D Supplier Manages REMS registry exclusively: No Wholesale distributor support: Small Quantity (49 CFR 173.4) No Special Permit; DOT-SP Provider Name: Site Enrollment Number assigned Special Provision (listed in Column 7 of 49 CFR 172.101); DEA #: by Supplier: No SP# PCPDP #: NPI#: No ADD'L STORAGE INFORMATION Is the Product... Comments Controlled Substance? No Controlled by State(s)? No Registry: ARCOS Reportable? No Registry Program Contact Name Schedule No. (inc. N for non-narcotic) Comments Controlled Substance Code Listed Chemical (List I or II) No RETURN INSTRUCTIONS If yes, indicate which: 732-529-0430 Is it a scheduled listed chemical product?: Contact tel. # if product received damaged: No CLASS OF TRADE RESTRICTION: Is product returnable for credit: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices No URL/Link to returns policy: contact - customerservice@camberpharma.com Restricted to retail pharmacy only: Yes No Special regulations or returns requirements for this product in certain states? Restricted to hospital, clinics, and physician offices only: No If so, which states? Other requirements? Comments? Restricted from US territories? (explain in comments) No Comments: MISCELLANEOUS 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:		Purchase order daily receipt cut off time by supplier				
a. EDI		Cut off time:	Eastern			
b. Autofax	Fax Number:					
c. Fax	Fax Number:	Shipping lead time of PO: Hours	Days			
d. Phone only	Phone No.:					
e. Supplier Web Site only	Site Address:	Ships same day for next day receipt:				
Minimum Order Quantity:		Ships for second day receipt:				
Supplier's Customer Service Number:	Nome	Ships regular ground for 3-10 days receipt:				
Contracted 3PL company / contact #:	Name: Phone:					
From a district Charles of the Charles		Occasion to the Control of the Contr				
	arges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Pro	bcessing			
Expedited freight fees billed with each ord	er:	Overnight receipt available:				
Drop Ship service fee billed with each orde	er:	PO Receipt cut off time:	Eastern			
Drop Ship miscellaneous fees billed:		Days of week overnight is available:	Monday			
Comments:			Tuesday			
			Wednesday			
			Thursday			
			Friday			
		Priority Overnight receipt available:				
Cl	ass of Trade Restriction:	PO Receipt Cut off time:				
No restriction: Select YES if sold to retail p	pharmacy, hospitals, clinics and physician offices	Saturday Overnight receipt available:				
Restricted to retail pharmacy only:		PO Receipt Cut off time:				
Restricted to hospital, clinics, and physicia	n offices only:	Order receipt method: Phone #:				
Restricted from US territories? (explain in	comments)	Fax: Fax #:				
Comments:		EDI:				
		Overnight Fees apply:				
		Other fees apply:				
Other Data In	formation Required to Process PO:	Return Instructions				
Patient Procedure Date:		Contact # if product is received damaged:				
Physician Name:		Is product returnable for credit:				
Physician/Clinic Phone #		URL/Link to returns policy:				
Physician State License #		Special regulations or returns requirements for this product in cer	tain states?			
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?				