

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

Version 2021						Introduction Type:	New Item	1	Final Version			Date:	8/5/	/2021
			PRODUCT INFORMA	TION					SPECIAL HA	NDLING AND STO	RAGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA					a. Temperature – Indicate the USP temperature range for this product.									
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 214616					Temperature Range Cold – between 2 and 8 C (36° – 46° F)									
Medical Device Class, if applicable:														
DUNS:	826774775								Other Temperature Range	Requirement				
Proprietary Name (If Applicable)	and Established N	ame: Fosar	prepitant Dimeglumine 150m	g/vial 10m/l				I	(write in)					
Selling Unit NDC:	31722-165-31		Unit of Use NDC:				2216531		Notes					
UDI			CVX Code:			MVX Code:		1						
Description: Powder for Injection (Intravenous), white to off white powder. When reconstituted, the color should be clear, colorless to a pale yellow solution. The									No	1				
clarity is clear.							Is this product to be shipp				No	1		
Active Ingredient(s): Fosaprepitant Dimeglumine														
						b. Contact fo	or temperature excursion q	uestions:						
URL for Additional Product Information: <u>www.camberpharma.com</u> Address: 800 Centennial Ave Address 2:					1	Name:		Soma Raju						
Address:	dress: 800 Centennial Ave y: Pisacataway State:			NJ	00054	-	Number: Group E-mail:		732-529-04					
City: Key Contact:	Customer Service	Δ	State:         NJ         08854           Email:         customerservice@camberpharma.com					Group E-mail: somaraju@heterousa.com						
Phone Number:	732-529-0430				Fax:	732-562-8788	amberpharma.com	c Special re	gulations for product in an	v states?				
Product Therapeutic Classification		Antiemetics						or openiar re	Special returns requireme	-				
l rouge merupouno ciacomouni									Openial retaine requireme	nto for ano product.				4
	ADDIT	IONAL PRODUCT IN	IFORMATION			PRODUCT DESC	RIPTION INFORMATION	d. Store prod	duct (unit of sale) upright?				No	1
The product is?			Is the Product	Direct-Ship C	Only			11	Protect product (unit of	sale) from light?			No	i
a legend device?		No	Is the Product	Neither			10m/l	e. Shelf life:	i rotect product (unit of :	sais) iroin light?			24	Months
if yes, enter class #		1.10	Orphan Drug Status			Size:		3. 3.1611 1176.	Initial shelf life at launch	(if different):			24	Months
a product kit?		No				04	150mg			(				
if yes, list NDCs of			FDA Approval Status			Strength:	_			ORDER INFORI	MATION			
component parts						Dosage Form:	Powder for Injection (Intrav							
reverse numbered?		No				2 coago : c			Unit of Sale			NDC selling	unit?	
co-licensed?		No	Allergens Present						Bottle		31722-165-			
latex-free?		Yes				Product Shape:	N/A		X Box/Carton		(Write-in, e	.g. 1 Box of 1	0 Vials)	
preservative-free? correctional institution block?		Yes Yes					White to off White		Ampule Glass		Minimum	rder quantity	,2	Yes
opioid?		Yes				Product Color:	writte to oil writte		Tube		William 0	ruer quantity	y :	162
Cannabinoid?		No	Country of Origin	India			N/A		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for		,g			Product Imprint:	1		Vial Liquid Multi		If Yes, how	many of wh	ich package	type?
hospital scanning?		No	Is this product covered u	inder the					Vial Powder Sql		1	Each		••
If Unit Dose, indicate NDC here:			Trade Agreements Act (	TAA)?	No				Vial Power Multi			Inner/Cartor	n/Pack	
								]	Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
					Au		uthorized Generic, other	PHARMACY ORDER / BILL UNIT						
I. Orange Book Rating:	AP					secti	on fields are not applicable	Rec. sell uni	t to customer?		Rx billing u	nit to pharm	асу:	
II. Generic Equivalent to What Br	and?:	Emend										Each		
		PRII CUPP	. V OUT IN OF OUR ITY A OF	(DOOO 4) INTEG				(Write-in, e.g	ı. 1 Vial)			Gram		
		DRUG SUPP	LY CHAIN SECURITY ACT	(DSCSA) INFOR	RMATION							Milliliter		
Does supplier meet DSCSA defir	sition of manufactu	ırar?	Yes	_	GLN:	0331722000000			ITE	M AND PACKING I	NEORMATIO	N		
Is product exempt from DSCSA?			No	$\dashv$	JLN.	033172200000				AIND I ACKING I	ORWATIO			
					CCD.			1		Dimena	ions (US msr	nte \	V-I	Calactic "
If yes, select exemption: Other exemption - Write in:					GCP:			1	Weight Lbs.	Dimens Depth	ions (US msr Width	nts.) Height	Volume (Cube)	Saleable # Pieces
Is product repackaged?			No		If yos was or	iginal product		Item/Each:					T .	
Is product sold by manufacturer	s exclusive distrib	utor?	No	$\dashv$		rect from mfr?		Aciny Edon.	0.02	2.5	1	1	2.5	1
Has FDA granted waiver/exception			No	7		ce manufacturer for repa	ckaged product	Box/Carton/I	Bundle/				0	
If yes, attach documentation fro	om FDA.							Inner Pack:					0	
								Case:	4.9	4	15	11	660	48
		GT	IN AND HIBCC PRODUCT I	NFORMATION					0	·			000	.0
Onlankia Hali at Managara								Pallet:					0	
Saleable Unit of Measure	;	Saleable Quantity	HIBCC			N-14 31722165310	Unit of Use GTIN-14							
X Item/Each Box/Carton/Bundle/Inner Pack					003	31122103310			COST INFORMATION			WHOLESAL	ER USE ONL	γ.
X Case		48			203	31722165314			OCCI IN CHIMATION			WITOLLOAL	ER OOL ON	
Pallet					203			Regular			Vendor #:			
								Invoice Cost	(WAC) (\$)	\$65.00	Whsl. Code	#:		
										,,,,,,	Fineline Co			
								As of date:						
								[]						
ļL								Ц						
1		_	Attach copy of SAFETY DA	ATA SHEET (SE	OS) or non haza		RT, LABEL AND PHOTO OF F	PRODUCT PACK						
*Please provide any additional in	iformation on page	2.				See new p. 3 for Design	nated Drop Ship Only.		Signature:					



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For Designated Drop Ship Only Products, Please Use Page 3

MA	TERIAL HAZ	ARD 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?  Does the product label bear a CA Prop 65 warning?	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:	No					
c. DOT Hazard Class		Hazardous Waste Identification					
d. Packing Group							
e. Inhalation Hazard?	No	EPA Hazardous Waste Code:		Waste Characteristics			
Is this product regulated for shipment by IATA?	No			-			
(if yes, answer a-e below and provide SDS)		REMS o	r REGISTRY RESTRICTIONS				
a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group		Is there a REMS on this product?  If Yes, is it managed with a pharmacy registry?  Website URL:	No				
e. Inhalation Hazard?	No						
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?)	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)	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#: NPI #:				
Special Permit; DOT-SP		Comments					
Special Provision (listed in Column 7 of 49 CFR 172.101);		Registry:	No				
Sr#		Registry Program Contact Name:	NO	Phone:			
ADD'L STORAGE INFORMATION		Comments		i none.			
Is the Product							
Controlled Substance? Controlled Substance? Controlled by State(s)? ARCOS Reportable? Schedule No.  No Listed Chemical (List I or II) If yes, indicate which: Is it a scheduled listed chemical product?:  CLASS OF TRADE RESTRICTION:	No No	Contact tel. # if product received damaged:  Is product returnable for credit:	1-866-827-3647 Yes				
	Yes	URL/Link to returns policy:					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	contact - customerse	rvice@camberpharma.com					
Restricted to retail pharmacy only:	Special regulations or returns requirements for this						
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)	product in certain states?  If so, which states? Other requirements? Comments?						
Comments:							
	ISCELLANEC	US NOTES and/or Image of Product Barcode:					



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#### Version 2021

#### FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated D	Orop 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:
	x Number:	
	x Number:	Shipping lead time of PO: Hours Days
	one No.:	China cama day far nayt day receipts
e. Supplier Web Site only Site Minimum Order Quantity:	e Address:	Ships same day for next day receipt: Ships for second day receipt:
Supplier's Customer Service Number:		Ships regular ground for 3-10 days receipt:
Contracted 3PL company / contact #: Name:		Ships regular ground for 5-10 days receipt.
Phone:		
Expedited Freight Charges or Other De	esignated 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:		Days of week overnight is available: Monday
Comments:		Tuesday
		Wednesday
		Thursday
		Friday
		Priority Overnight receipt available:
Class of Trade Restr	riction:	PO Receipt Cut off time:
No restriction: Select YES if sold to retail pharmacy, hospitals	c clinics and physician offices	Saturday Overnight receipt available:
Restricted to retail pharmacy only:	s, clinics and physician onices	PO Receipt Cut off time:
Restricted to hospital, clinics, and physician offices only:		Phone: Phone #:
Restricted from US territories? (explain in comments)		Order receipt method: Fax: Fax #:
Comments:		EDI:
		Overnight Fees apply:
		Other fees apply:
Other Data Information Require	ed 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 #		
Physician/Clinic DEA #:		Special regulations or returns requirements for this product in certain states?
Physician/Clinic Specialty:		If so, which states? Other requirements? Comments?
Miscellaneous No	otes:	
		ADDITIONAL INFORMATION
		Is product order for scheduled patient procedure?
		Is product order for restocking purposes?