

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

Version 2021						Introduction Type	: New Item		x Final Version			Date:	2/14/	1/2024
			PRODUCT INFORMA	TION					SPECIAL HA	NDLING AND STOR	RAGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA					a. Temperature – Indicate the USP temperature range for this product.									
						Controlled Room	– between 20	and 25 C (68	3° − 77° F)					
Medical Device Class, if applicable:														
DUNS:	11-856-3719								Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a		ame: Atorv	rastatin Calcium Tablets, USF					1	(write in)					
Selling Unit NDC:	31722-425-10		Unit of Use NDC:				1722425100	-	Notes					
UDI			CVX Code:			MVX Code:		1						
Description:	Atorvastatin Calci	ium Tablets, USP 20) mg						Is this product to be shipp				No	_
Annual Control of the						-	Is this product to be shipp	ed to customers on o	dry ice?		No	_		
Active Ingredient(s): Atorvastatin calcium trihydrate, USP						h Contact fo	or temperature excursion q	uactions						
URL for Additional Product Information: www.camberpharma.com						D. Comaci ic	Name:	uestions.	Soma Raju					
Address:		Ave (and) 800 Cente				Address 2:		†	Number:		732-529-042	23		
City:	Piscataway		State: NJ Zip: 08854				ip: 08854	Group E-mail: somaraju@heterousa.com						
Key Contact:	Customer Service	ė	Email: customerservice@camberpharma.com			mberpharma.com	1							
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special re	gulations for product in an	-			No	_
Product Therapeutic Classificatio	on:	HMG-CoA reducta	ase inhibitor (statin)						Special returns requireme	nts for this product?			No	
							ADIDEIAN NEGDIA EIAN							7
	ADDITI	IONAL PRODUCT IN	NFORMATION			PRODUCT DES	CRIPTION INFORMATION	d. Store pro	duct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship C	Only				Protect product (unit of	sale) from light?			No	
a legend device?		No	Is the Product	Neither		Size:	1000 ct	e. Shelf life:					24	Months
if yes, enter class # a product kit?		No	Orphan Drug Status				20 mg		Initial shelf life at launch	(if different):				Months
if yes, list NDCs of		INU	FDA Approval Status			Strength:	20 mg			ORDER INFORM	MATION			
component parts			, , , , , , , , , , , , , , , , , , ,			Danama Farmi	Film coated tablet							
reverse numbered?		No				Dosage Form:			Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						x Bottle		1 Bottle of 1			
latex-free?		Yes	Dairy, Lac	tose, Casein		Product Shape:	Oval, biconvex		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free? correctional institution block?		Yes					White to off-white		Ampule Glass		Minimum a			Yes
opioid?		No No				Product Color:	write to oil-write		Tube		winimum oi	rder quantity		res
Cannabinoid?		No	Country of Origin	India			Debossed with '20' on one		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for		,			Product Imprint:	side and 'A 54' on other		Vial Liquid Multi		If Yes, how	many of whi	ich package t	type?
hospital scanning?			Is this product covered to	under the			side		Vial Powder Sql		12	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (TAA)?	No				Vial Power Multi			Inner/Carton	ı/Pack	
								<u> </u>	Other: Write In			Case		
			FOR GENERIC DRUG PR	RODUCTS										
					Δ.	thorized Generic *If	Authorized Generic, other		В	HARMACY ORDER	/ BILL LINIT			
1	A.D.			_	AU		ction fields are not applicable	Dec cell uni	it to customer?	TIARMACT ORDER				
I. Orange Book Rating: II. Generic Equivalent to What Bra	AB	Lipitor						Rec. Sell uni	it to customer?		Rx billing u	nit to pharm	acy:	
II. Generic Equivalent to what Bra	anur.	Lipitoi						(Write-in, e.g	1 Vial)			Gram		
		DRUG SUPP	PLY CHAIN SECURITY ACT	(DSCSA) INFO	RMATION			(**************************************	g. 1 v.u.,			Milliliter		
												-		
Does supplier meet DSCSA defini		rer?	Yes		GLN:	0331722000000			ITE	M AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?			No					4						
If yes, select exemption:					GCP:				Weight Lbs.		ions (US msn	•	Volume	Saleable #
Other exemption - Write in:			Na					I	rreigin LDS.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?	e avalueiva diataile.	utor?	No Yes		If yes, was or direct from n	riginal product purcha	sed	Item/Each:	0.89	3	3	5.5	49.50	1
Is product sold by manufacturer's Has FDA granted waiver/exceptio			No Yes	-		nr ? ce manufacturer for re	nackaged product	Box/Carton/	Bundle/					
If yes, attach documentation from			110		Trovide sour	oc manaracturer for re	packagea product	Inner Pack:	Dunaic,					
, , , , , , , , , , , , , , , , , , , ,								Case:	11.2	12.5	9.5	6.5	771.88	12
		GT	TIN AND HIBCC PRODUCT I	INFORMATION					11.2	12.5	9.5	0.5	771.00	12
								Pallet:						
Saleable Unit of Measure	S	Saleable Quantity	HIBCC			N-14	Unit of Use GTIN-14							
X Item/Each Box/Carton/Bundle/Inner Pack		1			003	31722425100			COST INFORMATION			WHOLESAL	ER USE ONL	γ.
Box/Carton/Bundle/Inner Pack X Case		12			203	31722425104			- COST INFORMATION			MIOLEGAL	EN USE UNL	
Pallet					200	<u></u>		Regular Cos	st .		Vendor #:			
								Invoice Cost		\$200.00	Whsl. Code	#:		
								11			Fineline Co			
								As of date:			4			
								11						
 			Attack conv COAFETY C	ATA CHEET 'CO	20)	ad laws DAOKAGE ""	PEDT LADEL AND DUCTO OF	II	(ACING and DADOODE		——			
*Please provide any additional inf	formation on nace	2	Adacti copy of SAFETY D	AIA SHEET (SL	וט נטכ non naza		SERT, LABEL AND PHOTO OF signated Drop Ship Only.	FRODUCT PACK	Signature:					
provide any additional lill	page					CCC HCH P. 3 IOI DES	gcu Drop Jilip Olliy.		o.g.iuturo.					



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Version 2021

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?	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?	No No	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	No	Is the product a NIOSH hazardous drug? If yes, indicate which:	No			
c. DOT Hazard Class d. Packing Group		Hazardous Waste Identification				
e. Inhalation Hazard? Is this product regulated for shipment by IATA?	No No	EPA Hazardous Waste Code:		Waste Characteristics		
(if yes, answer a-e below and provide SDS) a. UN/Identification Number	140	REMS or REGISTRY RESTRICTIONS				
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? Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo	No No	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)	No			
Passenger & Cargo 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? (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 Special Provision (listed in Column 7 of 49 CFR 172.101); SP#		Comments Registry:	No			
ADD'L STORAGE INFORMATION		Registry Program Contact Name: Comments		Phone:		
Is the Product Controlled Substance? Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II)	No	RI	ETURN INSTRUCTIONS			
ARCOS Reportable? Schedule No. If yes, indicate which: Is it a scheduled listed chemical product?: CLASS OF TRADE RESTRICTION:	Yes	Contact tel. # if product received damaged: Is product returnable for credit: URL/Link to returns policy:	1-866-827-3647 Yes			
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Yes		rvice@camberpharma.com			
Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)	No No	Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?				
Comments:						
MI	ISCELLANEC	US NOTES and/or Image of Product Barcode:				



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

Order Method fo	r 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 e. Supplier Web Site only Minimum Order Quantity:	Fax Number: Fax Number: Phone No.: Site Address:	Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt:				
F	Name: Phone:	Ships regular ground for 3-10 days receipt:				
Expedited Freight Charg	ges 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				
		Priority Overnight receipt available:				
Class	of Trade Restriction:	PO Receipt Cut off time:				
No restriction: Select YES if sold to retail pharmacy only: Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician of Restricted from US territories? (explain in conficulty) Comments:	offices only:	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:				
Other Data Infor	rmation 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?				
Mis	scellaneous Notes:					
		ADDITIONAL INFORMATION				
		Is product order for scheduled patient procedure? Is product order for restocking purposes?				