

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

						Introduction '	Туре:	Post Launch Change	1	x Final Version			Date:	6/1/	2024
			PRODUCT INFORMAT	ION						SPECIAL HANI	DLING AND STOR	AGE REQUIF	REMENTS*		
Company Name:	Camber Pharmaceutic	als Inc				Applica	tion:	ANDA	a Tomporatus	re - Indicate the USP tempe	raturo rango for t	hie product			
Application Number for NDA/AN			·a)·	20	07616	Applica	tion.	ANDA	a. remperatur	Temperature Range	Controlled Room		and 25 C (6)	8° – 77° F)	
Medical Device Class, if applical		rio(k)(illea devic	·c).	E	01010				-	remperature realige	OGINIONIO TROOM	20111001120	uu 20 0 (0.	, ,,	
DUNS:	11-856-3719								1	Other Temperature Range I	Pequirement				
Proprietary Name (If Applicable) a		Rosuva	statin Calcium Tablets 10 m	na (hase)					1	(write in)	(equilement				
Selling Unit NDC:	31722-883-90	1105010	Unit of Use NDC:	ig (base)	31722-883-90	UPC:	3317228	83900	1	Notes					
UDI			CVX Code:			MVX Code:			1						
Description:	Decumentatio Calaium	Tablata 10 ma /b		-					i	la thia neadust to be objected		2		No	1
Description:	Rosuvastatin Calcium	rablets to mg (b)	ase)							Is this product to be shipped Is this product to be shipped				No	
Active Ingredient(s):	Ros	suvastatin calciun	n IISP						1	is this product to be shipped	i to customers on c	ily ice:		140	1
Active ingredient(s).	T C C	savastatii i calciuli	11, 001						b. Contact for	temperature excursion qu	estions:				
URL for Additional Product Inform	mation:	w.camberpharma	a.com							Name:		Soma Raju			
Address:	800 Centennial Ave, Si	uite 1				Address 2:			1	Number:		732-529-042	3		
City:	Piscataway				NJ	Zip:	08854	Group E-mail: somaraju@heterousa.com			<u>n</u>				
Key Contact:	Customer Service	vice Email:			customerservice	@camber	pharma.com								
Phone Number:	1-866-827-3647				Fax:	732-562-8788			c. Special reg	ulations for product in any	states?			No	
Product Therapeutic Classificatio	on: HM	G-CoA reductase	inhibitors (statins)							Special returns requirement	s for this product?			No	
					_										
	ADDITIONAL	L PRODUCT INF	ORMATION			PRODUCT	DESCRIPT	TION INFORMATION	d. Store produ	uct (unit of sale) upright?				No	1
The product is?			Is the Product	Direct-Ship	Only					Protect product (unit of sa	ale) from light?			No	ī
a legend device?	No		Is the Product	Unit of Use	,	0:	90	O ct	e. Shelf life:		,			24	Months
if yes, enter class #	1,110		Orphan Drug Status			Size:				Initial shelf life at launch (	if different):				Months
a product kit?	No		. •			Ctuomath.	10	0 mg		•	•				
if yes, list NDCs of			FDA Approval Status			Strength:		-			ORDER INFORM	IATION			
component parts						Dosage For	m· Fi	ilm coated tablet							
reverse numbered?	No					Dosage i oi				Unit of Sale		What is the		unit?	
co-licensed?	No		Allergens Present							x Bottle		1 Bottle of 90			
latex-free?	Yes					Product Sha		ound, bevel edged,		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?	Yes						-	convex		Ampule				_	
correctional institution block?	No					Product Col	or:	ght pink to pink		Glass		Minimum o	der quantit	/?	Yes
opioid? Cannabinoid?	No No		Country of Origin	India			D	ebossed with 'H' on one side		Tube Vial Liquid Sgl					
If Unit Dose, is item bar coded to u			Country of Origin	muia		Product Imp		nd 'R4' on the other side				If Voc. how	many of wh	ioh naakaaa	tumo?
hospital scanning?	unit dose for		Is this product covered ur	oder the						Vial Liquid Multi Vial Powder Sgl		If Yes, how	many or wn Each	ісп раскаде	type?
If Unit Dose, indicate NDC here:			Trade Agreements Act (T		No					Vial Powder Multi			Inner/Cartor	/Pack	
ii onii bose, indicate Nbo nere.			Trade rigidemente riot (1	, .	140				11	VIGIT OVVGCI IVIGILI			ii ii ici/ Cai toi	or acit	
										Other: Write In			Case		
			FOR GENERIC DRUG PRO	DUCTS					1	Other: Write In			Case		
		F	FOR GENERIC DRUG PRO	DUCTS					<u>]                                    </u>	Other: Write In			Case		
		F	FOR GENERIC DRUG PRO	DUCTS	Aufl	horized Generic	*If Autho	rized Generic other			ARMACY ORDER		Case		
L Orango Book Pating	AD	F	FOR GENERIC DRUG PRO	DUCTS	Auti	horized Generic		rized Generic, other ields are not applicable	Pac sell unit	PH.	ARMACY ORDER	/ BILL UNIT		2011	
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## **Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)**

#### Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply):  a. Cytotoxic?  b. CA Prop. 65 Carcinogen or Reproductive Toxicant?  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?  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?  Is this product regulated for shipment by DOT?  (if yes, answer a-e below and provide SDS)	SDS Hazard Classification  X Organic Oxidizer Oxidizer Contact Hazard  Does the product have an Aerosol class? If yes, identify NFPA Storage Level:  NFPA Storage Level:  Is the product a NIOSH hazardous drug?  If yes, indicate which:						
a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Hazardous Waste Identification  EPA Hazardous Waste Code:  Waste Characteristics						
Is this product regulated for shipment by IATA?  (if yes, answer a-e below and provide SDS)  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:						
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#  ADD'L STORAGE INFORMATION	Comments  Registry:  Registry Program Contact Name:  Comments  Phone:						
Is the Product	Comments						
Controlled Substance? Controlled Substance? Controlled Substance? Controlled Substance Code Listed Chemical (List I or II) No ARCOS Reportable? No If yes, indicate which: Is it a scheduled listed chemical product?: No CLASS OF TRADE RESTRICTION:	RETURN INSTRUCTIONS  Contact tel. # if product received damaged:  Is product returnable for credit:  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: Restricted from US territories? (explain in comments)  No Comments:	Special regulations or returns requirements for this product in certain states?  If so, which states? Other requirements? Comments?						
COHMITCHES.							
MISCELLANEC	DUS NOTES and/or Image of Product Barcode:						



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

#### Version 2021

### 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  Fax Number:	Purchase order daily receipt cut off time by supplier Cut off time:
c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number:	Shipping lead time of PO:  Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:
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:	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, 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: 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 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?
Miscellaneous Notes:	
	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure? Is product order for restocking purposes?