

## **Standard Pharmaceutical Product Information (Rx Product Only)**

© August 2014					Introduction Type:	Post Launch C	Change		Final Version			Date:	5/9/	/2017
			PRODUCT INFORMATION	N					SPECIAL HANDL	ING AND STO	RAGE REQ	JIREMENTS'	*	
Company Name:	Camber Pharmaceuti	cale			Applicati	on: AND	Δ	a. Temperature – Indica	ata tha USD tampar	atura ranga f	or this prod	ıot		
Application Number for ND			1	207616	Applicati	7440			ure Range	ature range i			en 20 and 25	5 C (68° – 77° F
		minoroto(k)(mea aevice)	·-	207010				-	=		CONTROLLOGIC	00111 201110	011 20 4114 20	70 (00 11 1
DUNS:	82-667-4775	. 1-							mperature Range Re	quirement				-
Proprietary Name (If Applical		Name: Rosuvast	tatin Calcium Tablets 10MG 90C		T I			(wri	te in)					
Selling Unit NDC:	31722-883-90		Individual Unit NDC:	31722-883-90		722883900								
UDI			CVX Code:		MVX Code:			Is this pro	duct to be shipped to	customers o	n ice?		No	_
Description:	Round, pink tablets e	mbossed with 'R4' on uppe	er punch and 'H' on lower					Is this pro	duct to be shipped to	customers o	n dry ice?		No	
Active Ingredient(s):		Rosuvastatin Calcium						b. Contact for tempera	ture excursion que	stions:				
								Name:			Soma Raju			
URL for Additional Product In	t Information: www.camberpharma.com 1031 Centennial Avenue			Address 2:			Number:			732-529-0423 somaraju@heterousa.com				
Address:		nue		21.11				Group E	-mail:		somaraju@r	eterousa.co	n	
City:	Piscataway State: NJ Zip: 08854							0			N1.			
Key Contact: Phone Number:	732-529-0430	Customer Service         Email:         customerservice@camberpharma.com           732-529-0430         Fax:         732-562-8788			perpharma.com		c. Special regulations for product in any states?  Special returns requirements for this product?  No				_			
				rax.	732-562-8788			Special re	eturns requirements i	or this produc	l?		INO	_
Product Therapeutic Classifi	ication:													
			,	_				d. Store product (unit o					No	_
ADDITIONA	AL PRODUCT INFORM	ATION		P	PRODUCT DESCRIPTION	NINFORMATION		Protect p	product (unit of sale	e) from light?			No	=
Is the Product								e. Shelf life:					24	Months
a legend device?		No		Size:	90			Initial she	elf life at launch (if o	different):				Months
reverse numbered?		No		Oile.	30									
co-licensed?		No		Strength:	10 mg				C	ORDER INFOR	RMATION			
Is the Product		Direct-Ship Only		oog										
Is the Product		Unit of Use		Dosage Form:	Oral solid table	t		Unit of S				NDC selling	unit?	
				_					Bottle		1 box of 24		0.15-1-1	
If Unit Dose, is item bar code	ed to unit dose for hosp	ital scanning?						x	Box/Carton		(vvrite-in, e.	g. 1 Box of 1	u viais)	
If Unit Dose NDC, indicate NI	DC h			Product Shape	e: round				Ampule Glass		Min.:	der quantity	-2	Yes
II Unit Dose NDC, Indicate No	DC nere:								Tube		Wilnimum o	der quantity	1	res
Country of Origin		India		Product Color:	pink				Vial Liquid Sgl					
									Vial Liquid Multi		If Yes, how	many of whi	ch package	type?
Is this product covered under	r the Trade Agreements	Act (TAA)?		Product Imprin	nt: R4'/'H'				Vial Powder Sql			Each		71
									Vial Power Multi			Inner/Cartor	/Pack	
									viai i Owei iviulii					
									Other: Write In	_	24	Case		
			FOR GENERIC DRUG PRODU	UCTS							24		or don	
			FOR GENERIC DRUG PRODU						Other: Write In	1		Case		
			FOR GENERIC DRUG PRODU			Authorized Generic, other	er section		Other: Write In	MACY ORDE		Case	. r uun	
I. Orange Book Rating:	AB		FOR GENERIC DRUG PRODU			Authorized Generic, other ds are not applicable	er section	Rec. sell unit to custon	Other: Write In	MACY ORDE	R / BILL UNI	Case		
I. Orange Book Rating:		Crestor	FOR GENERIC DRUG PRODU				er section	Rec. sell unit to custon	Other: Write In	RMACY ORDE	R / BILL UNI	Case  T  nit to pharm  Each		
				Autho			er section		Other: Write In	MACY ORDE	R / BILL UNI	Case  T  nit to pharm  Each  Gram		
			FOR GENERIC DRUG PRODU	Autho			er section	Rec. sell unit to custon	Other: Write In	RMACY ORDE	R / BILL UNI	Case  T  nit to pharm  Each		
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## **Standard Pharmaceutical Product Information (Page 2)**

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL I	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 GIAGGIRIGATORI	
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	
a Contact Haranda	A arread Class Identify NEDA Ctarage Levels	
c. Contact Hazard?	Aerosol Class; Identify NFPA Storage Level:	
d. Does this product require special clean-up instructions?		
(If yes, attach SDS with special instructions.)	Is the product a NIOSH hazardous drug?	
e. Does the product contain DEHP?	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		
b. Proper Shipping Name	Hazardous Waste Identification	
c. DOT Hazard Class	EPA Hazardous Waste Code: NA	
d. Packing Group		
e. Inhalation Hazard?		
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:	
	Website ORL.	
Is this a reportable quantity? No		
RQ Threshold:	Comments / Details: (For example, iPledge program?)	
Is this a marine pollutant? No		
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 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	)
<u></u>	NPI #: No	)
ADD'L STORAGE INFORMATION		
Is the Product	Comments	
Controlled Substance? No		
Controlled by State(s)?	Registry: No	
ARCOS Reportable? No	Registry Program Contact Name: Phone:	
Schedule No. (inc. N for non-narcotic)	Comments	
Controlled Substance Code		
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:	
N c c		
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	Special regulations or returns requirements for this product in certain states?  No	
Restricted to hospital, clinics, and physician offices only:	If so, which states? Other requirements? Comments?	
Restricted from US territories? (explain in comments)  No		
Comments:		
MISCELLAI	ANEOUS 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?				