



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

Version 2024

Introduction Type:  New Item

Final Version

Date: 7/24/2024

## PRODUCT INFORMATION

Company Name: Camber Pharmaceuticals, Inc. Application: ANDA  
 Application Number for NDA/ANDA/BLA: PMAJ510(K): 214344 NOT APPLICABLE  
 Medical Device Class, if applicable: NDA 505(b) Type: NOT APPLICABLE  
 DUNS: 11-856-3719  
 Proprietary Name (if Applicable) and Established Name: Atorvastatin Calcium Tablets, USP 80 mg  
 Selling Unit NDC: 31722-427-90 Unit of Use NDC: 331722427906  
 CVX Code: MXV Code:  
 Description: Atorvastatin Calcium Tablets, USP 80 mg  
 Active Ingredient(s): Atorvastatin calcium trihydrate, USP  
 URL for Additional Product Information: www.camberpharma.com  
 Address: 800 Centennial Ave, Suite 1  
 City: Piscataway State: NJ Zip: 08854  
 Key Contact: Customer Service Email: customerservice@camberpharma.com  
 Phone Number: 1-866-827-3647 Fax: 732-562-5788  
 Product Therapeutic Classification: HMG-CoA reductase inhibitor (statin)

## SPECIAL HANDLING AND STORAGE REQUIREMENTS\*

a. Temperature -- Indicate the USP temperature range for this product.  
 Temperature Range: Controlled Room -- between 20 and 25 C (68° -- 77° F)  
 Other Temperature Range Requirement (write in):  
 Notes:  
 Is this product to be shipped to customers on ice? No  
 Is this product to be shipped to customers on dry ice? No  
 b. Contact for temperature excursion questions:  
 Name: Soma Raju  
 Number: 732-529-0423  
 Group E-mail: somaraju@heterousa.com  
 c. Special regulations for product in any states?  
 Special returns requirements for this product?  
 No  
 No  
 d. Store product (unit of sale) upright?  
 Protect product (unit of sale) from light?  
 Initial shelf life at launch (if different):  
 No  
 No  
 24  
 Months  
 Months

## ADDITIONAL PRODUCT INFORMATION

The product is?  No  Direct-Ship Only  
 Is the product...  No  Unit of Use  
 Orphan Drug Status  No  Unit of Use  
 FDA Approval Status  No  Unit of Use  
 Allergens Present  No  Dairy, Lactose, Casein  
 Country of Origin  No  India  
 Is this product covered under the Trade Agreements Act (TAA)?  No  No  
 Cannabinoid?  No  
 If Unit Dose, is item bar coded to unit dose for hospital scanning?  
 If Unit Dose, indicate NDC here:

## PRODUCT DESCRIPTION INFORMATION

Size: 90 ct  
 Strength: 80 mg  
 Dosage Form: Film coated tablet  
 Product Shape: Oval, biconvex  
 Product Color: White to off-white  
 Product Imprint: Debossed with '80' on one side and 'A 56' on other side

## ORDER INFORMATION

Unit of Sale:  Bottle  
 Box/Carton  
 Ampule  
 Glass  
 Tube  
 Vial Liquid Sgl  
 Vial Liquid Multi  
 Vial Powder Sgl  
 Vial Powder Multi  
 Other: Write In  
 What is the NDC selling unit?  
 1 Bottle of 90 Tablets  
 (Write-in, e.g. 1 Box of 10 Vials)  
 Minimum order quantity?  Yes  No  
 If Yes, how many of which package type?  
 Each: 24  
 Inner/Carton/Pack:   
 Case:

## FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: AB  Authorized Generic  \*If Authorized Generic, other section fields are not applicable  
 II. Generic Equivalent to What Brand?: Lipitor

## DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?  Yes  No  
 Is product exempt from DSCSA?  
 If yes, select exemption:  
 Other exemption - Write in:  
 Is product repackaged?  
 Is product sold by manufacturer's exclusive distributor?  
 Has FDA granted waiver/exemption/exemption for product?  
 If yes, attach documentation from FDA,  
 GLN: 0331722498975  
 GCP:  No  Yes  
 If yes, was original product purchased direct from mfr?  
 Provide source manufacturer for repackaged product

## GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	RFID tag(V/N)	Saleable Quantity	GTIN-14	Unit of Use GTIN-14
X Item/Each	N	1	00331722427906	00331722427906
X Box/Carton/Bundle/Inner Pack	N	24	20331722427900	
Case				
Pallet				

## PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?  
 Rx billing unit to pharmacy:  
 Each  
 Gram  
 Milliliter  
 (Write-in, e.g. 1 Vial)  
 HCPCS L-Code:

## ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)	Volume (Cube)	Saleable # Pieces
		Depth Width Height		
Box/Carton/Bundle/Inner Pack:	0.36	2.2 2.2 4.75	22.99	1
Case:	9.35	13.6 9.4 5.75	735.08	24
Pallet:				

## COST INFORMATION

Regular Cost Invoice Cost (WAC) (\$)  
 As of date: 2/5/2024  
 Vendor #: \$18.00  
 Whsl. Code #:  
 Finaline Code:

\*Please provide any additional information on page 2.

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter. PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE. Signature: \_\_\_\_\_

See new p. 3 for Designated Drop Ship Only.



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For Designated Drop Ship Only Products, Please Use Page 3

## MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

- a. Cytotoxic?  No
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?  No
- Is the product a CA Prop 65 carcinogen?  No
- Is the product a CA Prop 65 reproductive toxicant?  No
- Does the product label bear a CA Prop 65 warning?  No

- c. Contact Hazard?  No
- d. Does this product require special clean-up instructions?  No
- (If yes, attach SDS with special instructions.)
- e. Does the product contain DEHP?  No

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
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard?

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 the product restricted for air shipment? If so, indicate restriction:

Passenger  No

Cargo

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?

No  (if yes, identify method below)

Limited Quantity

Consumer Commodity, ORM-D

Small Quantity (49 CFR 173.4)

Special Permit: DOT-SP

Special Provision (listed in Column 7 of 49 CFR 172.101):

SP#

## ADD'L STORAGE INFORMATION

Is the Product...

Controlled Substance?  No

Controlled by State(s)?  No

ARCOS Reportable?  No

Schedule No.

Controlled Substance Code

Listed Chemical (List I or II)

If yes, indicate which:

Is it a scheduled listed chemical product?:  No

## CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes

Restricted to retail pharmacy only:  No

Restricted to hospital, clinics, and physician offices only:  No

Restricted from US territories? (explain in comments)  No

Comments:

## SDS Hazard Classification

- Organic
- Inorganic
- Steroid/Androgen
- Corrosive
- 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.

## Hazardous Waste Identification

EPA Hazardous Waste Code:  Waste Characteristics

## REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?  No

If Yes, is it managed with a pharmacy registry?

Website URL:

Med Guide Required  No

Limited Distribution Requirement

Comments / Details: (For example, iPledge program?)

REMS:

REMS Program Manager Name:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name:

Site Enrollment Number assigned by Supplier:

DEA #:

NCPDP#:

NPI #:

Comments

Registry:  No

Registry Program Contact Name:

Comments

Phone:

## RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

1-866-827-3647

Is product returnable for credit:  Yes

URL/Link to returns policy:

contact - customerservice@camberpharma.com

Special regulations or returns requirements for this product in certain states?  No

If so, which states? Other requirements? Comments?

## MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE



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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										
<p>Purchase orders may be accepted by:</p> <p>a. EDI <input type="text"/></p> <p>b. Autofax <input type="text"/></p> <p>c. Fax <input type="text"/></p> <p>d. Phone only <input type="text"/></p> <p>e. Supplier Web Site only <input type="text"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/></p> <p>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Phone No.: <input type="text"/></p> <p>Site Address: <input type="text"/></p>	<p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="text"/></p> <p>Ships for second day receipt: <input type="text"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="text"/></p>										
<p><b>Expedited Freight Charges or Other Designated Drop Ship Fees:</b></p> <p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input type="text"/></p>	<p><b>Overnight and Priority Overnight PO Processing</b></p> <p><b>Overnight receipt available:</b></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <table border="1"> <tr><td><input type="checkbox"/></td><td>Monday</td></tr> <tr><td><input type="checkbox"/></td><td>Tuesday</td></tr> <tr><td><input type="checkbox"/></td><td>Wednesday</td></tr> <tr><td><input type="checkbox"/></td><td>Thursday</td></tr> <tr><td><input type="checkbox"/></td><td>Friday</td></tr> </table>	<input type="checkbox"/>	Monday	<input type="checkbox"/>	Tuesday	<input type="checkbox"/>	Wednesday	<input type="checkbox"/>	Thursday	<input type="checkbox"/>	Friday
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<input type="checkbox"/>	Friday										
<p><b>Class of Trade Restriction:</b></p> <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices</p> <p>Restricted to retail pharmacy only: <input type="text"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="text"/></p> <p>Restricted from US territories? (explain in comments) <input type="text"/></p> <p>Comments: <input type="text"/></p>	<p><b>Priority Overnight receipt available:</b></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Phone #: <input type="text"/></p> <p>Fax #: <input type="text"/></p> <p>EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="text"/></p> <p>Other fees apply: <input type="text"/></p>										
<p><b>Other Data Information Required to Process PO:</b></p> <p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p><b>Return Instructions</b></p> <p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="text"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="text"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>										
<p><b>Miscellaneous Notes:</b></p> <p><input type="text"/></p>											
<p><b>ADDITIONAL INFORMATION</b></p> <p>Is product order for scheduled patient procedure? <input type="text"/></p> <p>Is product order for restocking purposes? <input type="text"/></p>											