



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

Version 2024

Introduction Type:  New Item

Final Version

Date: 7/25/2024

## 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 10 mg  
 Selling Unit NDC: 31722-424-10 Unit of Use NDC: 331722424103  
 CVX Code: MXV Code:  
 Description: Atorvastatin Calcium Tablets, USP 10 mg  
 Active Ingredient(s): Atorvastatin calcium trihydrate, USP  
 URL for Additional Product Information: [www.camberpharma.com](http://www.camberpharma.com)  
 Address: 800 Centennial Ave, Suite 1  
 City: Piscataway State: NJ Zip: 08854  
 Key Contact: Customer Service Email: [customerservice@camberpharma.com](mailto: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.  
 Controlled Room -- between 20 and 25 C (68° -- 77° F)  
 Temperature Range  
 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](mailto: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?  
 No  
 No  
 e. Shelf life:  
 Initial shelf life at launch (if different):  
 Months: 24  
 Months:

## ADDITIONAL PRODUCT INFORMATION

The product is?  Is the Product...  Direct-Ship Only  
 a legend device?  Is the Product...  Orphan Drug Status  
 if yes, enter class #  Neither  
 a product kit?  No  
 if yes, list NDCs of component parts  No  
 reverse numbered?  No  
 co-licensed?  No  
 latex-free?  Yes  
 preservative-free?  Yes  
 correctional institution block?  No  
 opioid?  No  
 Cannabinoid?  No  
 Country of Origin: India  
 If Unit Dose, is item bar coded to unit dose for hospital scanning?  No  
 If Unit Dose, indicate NDC here:  No

## PRODUCT DESCRIPTION INFORMATION

Size: 1000 ct  
 Strength: 10 mg  
 Dosage Form: Film coated tablet  
 Product Shape: Oval, biconvex  
 Product Color: White to off-white  
 Product Imprint: Debossed with "10" on one side and "A 53" on other side

## FOR GENERIC DRUG PRODUCTS

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

## DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?  Yes  No  
 Is product exempt from DSCSA?  Yes  No  
 If yes, select exemption:  GLN: 0031722498975  
 Other exemption - Write in:  GCP:  
 Is product repackaged?  No  
 Is product sold by manufacturer's exclusive distributor?  Yes  
 Has FDA granted waiver/exemption/exemption for product?  No  
 If yes, attach documentation from FDA,

## 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	00331722424103	
X Box/ Carton/ Bundle/ Inner Pack	N	12	20331722424107	
X Case				
X Pallet				

## 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 1000 Tablets  
 (Write-in, e.g. 1 Box of 10 Vials)  
 Minimum order quantity?  Yes  
 If Yes, how many of which package type?  
 Each: 12  
 Inner/ Carton/ Pack:

## PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?  
 Rx billing unit to pharmacy:  
 Each  
 Gram  
 Milliliter  
 HCP/CS 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:	0.5	2.5	2.5	4
Case:	6.2	10.5	8	5.5
Pallet:				12

## COST INFORMATION

Regular Cost Invoice Cost (WAC) (\$): \$133.33  
 Vendor #:   
 Whsl. Code #:   
 As of date: 2/5/2024  
 Finaline Code:

## WHOLESALE USE 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? (if yes, attach SDS with special instructions.)  No
- 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
- Cargo
- Passenger & Cargo

Is this a reportable quantity?  No

RQ Threshold:  No

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.  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

- Restricted to retail pharmacy only:  Yes
- 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.

No

NFPA Storage Level:

Is the product a NIOSH hazardous drug? If yes, indicate which:

No

## Hazardous Waste Identification

EPA Hazardous Waste Code:

Waste Characteristics

## REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:

No

Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)

No

## REMS:

REMS Program Manager Name:  Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name:  DEA #:

Site Enrollment Number assigned by Supplier:  NCPDP#:

NPI #:

Comments

## Registry:

Registry Program Contact Name:  Phone:

No

## 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
Purchase orders may be accepted by: a. EDI b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #:	Purchase order daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:
Expedited Freight Charges or Other Designated Drop Ship Fees: Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight and Priority Overnight PO Processing Overnight receipt available: PO Receipt cut off time: Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday Priority Overnight receipt available: PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: Phone #: Fax #: EDI: Overnight Fees apply: Other fees apply:
Class of Trade Restriction: 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:	Return Instructions 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:
Other Data Information Required to Process PO: Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:	ADDITIONAL INFORMATION Is product order for scheduled patient procedure? Is product order for restocking purposes?
Miscellaneous Notes:	