



# 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  
 Medical Device Class, if applicable: PMA/510(K): 215761 NOT APPLICABLE  
 DUNS: 11-856-3719  
 Proprietary Name (if Applicable) and Established Name: Solifenacin Succinate Tablets 10 mg  
 Selling Unit NDC: 31722-025-30 Unit of Use NDC: 331722028301  
 CVX Code: 31722-025-30  
 Description: Solifenacin Succinate Tablets 10 mg  
 Active Ingredient(s): Solifenacin succinate  
 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: Muscarinic antagonist

## 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: Excursions permitted to 15°C to 30°C (59°F to 86°F)  
 Notes: (write in)  
 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  
 d. Store product (unit of sale) upright?  
 Protect product (unit of sale) from light? No  
 Initial shelf life at launch (if different):  
 Months: 24  
 Months: 24

## ADDITIONAL PRODUCT INFORMATION

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

Size: 30 ct  
 Strength: 10 mg  
 Dosage Form: Tablet  
 Product Shape: Round, biconvex  
 Product Color: White to off-white  
 Product Imprint: Debossed 'V' on one side and '19' on other side

## ORDER INFORMATION

Unit of Sale: x  
 Bottle: 1 Bottle of 30 Tablets  
 Box/Carton: (Write-in, e.g. 1 Box of 10 Vials)  
 Ampule:  
 Glass:  
 Tube:  
 Vial Liquid Sgl:  
 Vial Liquid Multi:  
 Vial Powder Sgl:  
 Vial Powder Multi:  
 Other: Write In  
 Minimum order quantity? Yes  
 If Yes, how many of which package type?  
 Each: 24  
 Inner/Carton/Pack:  
 Case:

## FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: AB  
 II. Generic Equivalent to What Brand?: Vesicare  
 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?  
 If yes, select exemption:  
 Other exemption - Write in:  
 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.

## ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Depth	Width	Height	Volume (Cube)	Saleable # Pieces
Box/Carton/Bundle/Inner Pack:	0.05	1.48	1.48	2.55	5.59	1
Case:	1.7	9.75	6.8	4	265.20	24
Pallet:						

## GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	RFID tag(V/N)	Saleable Quantity
x Item/Each	N	1
x Box/Carton/Bundle/Inner Pack	N	24
x Case		
x Pallet		

GTIN-14: 00331722028301  
 Unit of Use GTIN-14: 00331722028301  
 HIBCC: 20331722028305

## COST INFORMATION

Regular Cost Invoice Cost (WAC) (\$): \$10.00  
 Vendor #: \$10.00  
 Whsl. Code #: \$10.00  
 As of date: 9/29/2022  
 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?  No

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?  No

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

- Passenger
- 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? If Yes, is it managed with a pharmacy registry? Website URL:

Med Guide Required  No  
Limited Distribution Requirement  No  
Comments / Details: (For example, iPledge program?)

## REMS:

REMS Program Manager Name:  Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name:

Site Enrollment Number assigned by Supplier:

DEA #:

NCPDP#:

NPI #:

Comments

## Registry:

Registry Program Contact Name:  Phone:

Comments

## RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

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:	(Empty field for miscellaneous notes)