



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) | 215761 | NOT APPLICABLE
 Medical Device Class, if applicable:
 DUNS: 11-856-3719
 Proprietary Name (if Applicable) and Established Name: Solifenacin Succinate Tablets 5 mg
 Selling Unit NDC: 31722-027-30 | Unit of Use NDC: 331722027304
 UPC: 31722-027-30 | MXX Code:
 Description: Solifenacin Succinate Tablets 5 mg
 Active Ingredient(s): Solifenacin succinate
 URL for Additional Product Information: www.camberpharma.com
 Address: 800 Centennial Ave, Suite 1
 City: Piscataway
 Key Contact: Customer Service
 Phone Number: 1-866-827-3647
 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 (write in):
 Excursions permitted to 15°C to 30°C (59°F to 86°F)
 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
 Months 24
 Months

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 Trade Agreements Act (TAA)? No
 Cannabinoid?
 If Unit Dose, is item bar coded to unit dose for hospital scanning?
 If Unit Dose, indicate NDC here:
 Size: 30 ct
 Strength: 5 mg
 Dosage Form: Tablet
 Product Shape: Round, biconvex
 Product Color: White to off-white
 Product Imprint: Debossed 'V' on one side and '18' on other side

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?: Vesicare

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:
 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	00331722027304	00331722027304
X Box/Carton/Bundle/Inner Pack	N	24	20331722027308	
X Case				
X Pallet				

ORDER INFORMATION

Unit of Sale: x
 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 30 Tablets
 (Write-in, e.g. 1 Box of 10 Vials)
 Minimum order quantity?
 Yes
 If Yes, how many of which package type?
 Each 24
 Inner/Carton/Pack
 Case

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?
 Rx billing unit to pharmacy:
 Each
 Gram
 Milliliter
 HCP's L-Code:

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:						

COST INFORMATION

Regular Cost Invoice Cost (WAC) (\$)
 As of date: 9/29/2022
 Vendor #:
 Whsl. Code #:
 Final Code:
 WHOLESALER USE ONLY:

*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? No

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:

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:	