



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

Version 2024

Introduction Type: New Item

☒ Final Version

Date: 6/26/2026

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: Camber Pharmaceuticals, Inc.				Application: ANDA			
Application Number for NDA/ANDA/BLA; PMA/510(k): 205646				NDA 505(b) Type: NOT APPLICABLE			
Medical Device Class, if applicable:							
DUNS: 11-856-3719							
Proprietary Name (If Applicable) and Established Name: Tolvaptan Tablets 30 mg							
Selling Unit NDC: 31722-869-03				Unit of Use NDC:			
UDI				UPC: 331722869034			
CVX Code:				MVX Code:			
Description: Tolvaptan Tablets 30 mg							
Active Ingredient(s): Tolvaptan							
URL for Additional Product Information: www.camberpharma.com							
Address: 800 Centennial Ave, Suite 1				Address 2:			
City: Piscataway				State: NJ Zip: 08854			
Key Contact: Customer Service				Email: customerservice@camberpharma.com			
Phone Number: 1-866-827-3647				Fax: 732-562-8788			
Product Therapeutic Classification: Selective vasopressin V ₂ -receptor antagonist							
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
The product is?		Is the Product...		Size:			
a legend device?		Direct-Ship Only		10 ct			
if yes, enter class #		Unit Dose		30 mg			
a product kit?		Orphan Drug Status		Strength:			
if yes, list NDCs of component parts				Dosage Form:			
reverse numbered?				Tablet			
co-licensed?				Product Shape:			
latex-free?				Round, bevel edged, biconvex			
preservative-free?				Product Color:			
correctional institution block?				Blue			
opioid?				Product Imprint:			
Cannabinoid?				Debossed with "H" on one side and "T10" on the other side			
If Unit Dose, is item bar coded to unit dose for hospital scanning?		Yes					
If Unit Dose, indicate NDC here:		31722-869-31					
		Is this product covered under the Trade Agreements Act (TAA)?		No			
FOR GENERIC DRUG PRODUCTS							
I. Orange Book Rating: AB1				☐ Authorized Generic *If Authorized Generic, other section fields are not applicable			
II. Generic Equivalent to What Brand?: Samsca							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer? Yes				GLN: 0331722498975			
Is product exempt from DSCSA? No							
If yes, select exemption:				GCP:			
Other exemption - Write in:							
Is product repackaged? No				If yes, was original product purchased direct from mfr?			
Is product sold by manufacturer's exclusive distributor? Yes				Provide source manufacturer for repackaged product			
Has FDA granted waiver/exception/exemption for product? No							
If yes, attach documentation from FDA.							
GTIN AND HIBCC PRODUCT INFORMATION							
Saleable Unit of Measure		RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14	
☒ Item/Each		N	1		00331722869034		
☒ Box/ Carton/Bundle/Inner Pack		N	24		20331722869038		
☒ Case							
☒ Pallet							
ITEM AND PACKING INFORMATION							
	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces	
		Depth	Width	Height			
Item/Each:	0.05	4.6	1.1	1.82	9.21	1	
Box/ Carton/Bundle/ Inner Pack:							
Case:	1.8	9.75	7.5	4.5	329.06	24	
Pallet:							
COST INFORMATION				WHOLESALE USE ONLY:			
Regular Cost				Vendor #:			
Invoice Cost (WAC) (\$)				Whsl. Code #:			
As of date: 6/1/2022				Fineline Code:			

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

*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature:



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

Version 2024

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?

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?

No

(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?

No

(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:

No

☐ 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 Substance Code

Controlled by State(s)?

No

Listed Chemical (List I or II)

No

ARCOS Reportable?

No

If yes, indicate which:

Schedule No.

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:

No

NFPA Storage Level:

Is the product a NIOSH hazardous drug?

No

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:

No

REMS Program Manager Name:

Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name:

DEA #:

Site Enrollment Number assigned

NCPDP#:

by Supplier:

NPI #:

Comments

Registry:

No

Registry Program Contact Name:

Phone:

Comments

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



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

Version 2024

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 #: Name: Phone: Fax Number: Fax Number: Phone No.: Site Address:	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: Order receipt method: Phone: Phone #: Fax: 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:	
Other Data Information Required to Process PO: Patient Procedure Date: Physician Name: Physician/Clinic Phone #: Physician State License #: Physician/Clinic DEA #: Physician/Clinic Specialty:	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?
Miscellaneous Notes:	ADDITIONAL INFORMATION Is product order for scheduled patient procedure? ☐ Is product order for restocking purposes? ☐