



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

Version 2021

Introduction Type: Post Launch Change

Final Version

Date: 11/19/2024

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: <input type="text" value="Camber Pharmaceuticals, Inc."/>		Application: <input type="text" value="ANDA"/>		a. Temperature – Indicate the USP temperature range for this product.			
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): <input type="text" value="202682"/>				Temperature Range: <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/>			
Medical Device Class, if applicable: <input type="text"/>				Other Temperature Range Requirement (write in): <input type="text"/>			
DUNS: <input type="text" value="11-856-3719"/>				Notes: <input type="text"/>			
Proprietary Name (If Applicable) and Established Name: <input type="text" value="Atomoxetine Hydrochloride Capsules, USP 60 mg"/>				Is this product to be shipped to customers on ice? <input type="text" value="No"/>			
Selling Unit NDC: <input type="text" value="31722-718-30"/>		Unit of Use NDC: <input type="text" value="31722-718-30"/>		Is this product to be shipped to customers on dry ice? <input type="text" value="No"/>			
UDI: <input type="text"/>		CVX Code: <input type="text"/>					
Description: <input type="text" value="Atomoxetine Hydrochloride Capsules, USP 60 mg"/>		MVX Code: <input type="text"/>					
Active Ingredient(s): <input type="text" value="Atomoxetine hydrochloride, USP"/>				b. Contact for temperature excursion questions:			
URL for Additional Product Information: <input type="text" value="www.camberpharma.com"/>				Name: <input type="text" value="Soma Raju"/>			
Address: <input type="text" value="800 Centennial Ave, Suite 1"/>		Address 2: <input type="text"/>		Number: <input type="text" value="732-529-0423"/>			
City: <input type="text" value="Piscataway"/>		State: <input type="text" value="NJ"/>		Group E-mail: <input type="text" value="somaraju@heterousa.com"/>			
Key Contact: <input type="text" value="Customer Service"/>		Zip: <input type="text" value="08854"/>					
Phone Number: <input type="text" value="1-866-827-3647"/>		Email: <input type="text" value="customerservice@camberpharma.com"/>					
Product Therapeutic Classification: <input type="text" value="Selective norepinephrine reuptake inhibitor (SNRI)"/>		Fax: <input type="text" value="732-562-8788"/>		c. Special regulations for product in any states?			
				Special returns requirements for this product? <input type="text" value="No"/>			
				d. Store product (unit of sale) upright?			
				Protect product (unit of sale) from light? <input type="text" value="No"/>			
				e. Shelf life:			
				Initial shelf life at launch (if different): <input type="text" value="24"/> Months			
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
The product is a legend device? <input type="text" value="No"/>		Is the Product... Direct-Ship Only <input type="text"/>		Size: <input type="text" value="30 ct"/>			
if yes, enter class # <input type="text"/>		Is the Product... Unit of Use <input type="text"/>		Strength: <input type="text" value="60 mg"/>			
a product kit? <input type="text" value="No"/>		Orphan Drug Status <input type="text"/>		Dosage Form: <input type="text" value="Hard gelatin capsule"/>			
if yes, list NDCs of component parts reverse numbered? <input type="text"/>		FDA Approval Status <input type="text"/>		Product Shape: <input type="text" value="Capsule"/>			
co-licensed? <input type="text" value="No"/>		Allergens Present <input type="text" value="Animal Products"/>		Product Color: <input type="text" value="Blue opaque cap and yellow body"/>			
latex-free? <input type="text" value="Yes"/>		Country of Origin: <input type="text" value="India"/>		Product Imprint: <input type="text" value="Imprinted with '1' on cap and '109' on body"/>			
preservative-free? <input type="text" value="Yes"/>		Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="No"/>					
correctional institution block? <input type="text" value="No"/>							
opioid? <input type="text" value="No"/>							
Cannabinoid? <input type="text" value="No"/>							
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="text"/>							
If Unit Dose, indicate NDC here: <input type="text"/>							
FOR GENERIC DRUG PRODUCTS							
I. Orange Book Rating: <input type="text" value="AB"/>		Authorized Generic <input type="checkbox"/>		*If Authorized Generic, other section fields are not applicable			
II. Generic Equivalent to What Brand?: <input type="text" value="Strattera"/>							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer? <input type="text" value="Yes"/>		GLN: <input type="text" value="0331722498975"/>					
Is product exempt from DSCSA? <input type="text" value="No"/>		GCP: <input type="text"/>					
If yes, select exemption: <input type="text"/>		If yes, was original product purchased direct from mfr? <input type="text"/>					
Other exemption - Write in: <input type="text"/>		Provide source manufacturer for repackaged product <input type="text"/>					
Is product repackaged? <input type="text" value="No"/>							
Is product sold by manufacturer's exclusive distributor? <input type="text" value="Yes"/>							
Has FDA granted waiver/exception/exemption for product? <input type="text" value="No"/>							
If yes, attach documentation from FDA. <input type="text"/>							
GTIN AND HIBCC PRODUCT INFORMATION							
Saleable Unit of Measure		Saleable Quantity		HIBCC		GTIN-14	
<input checked="" type="checkbox"/> Item/Each		<input type="text" value="1"/>				<input type="text" value="00331722718301"/>	
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack						<input type="text" value="20331722718305"/>	
<input checked="" type="checkbox"/> Case		<input type="text" value="24"/>				Unit of Use GTIN-14 <input type="text" value="00331722718301"/>	
<input type="checkbox"/> Pallet							
COST INFORMATION				WHOLESALE USE ONLY:			
Regular Cost <input type="text"/>		Invoice Cost (WAC) (\$) <input type="text" value="\$53.10"/>		Vendor #: <input type="text"/>		Whsl. Code #: <input type="text"/>	
As of date: <input type="text" value="12/1/2024"/>				Fineline Code: <input type="text"/>			

*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.

See new p. 3 for Designated Drop Ship Only.

Signature:



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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?
 - 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 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 Yes Controlled Substance Code
- Controlled by State(s)? No Yes Listed Chemical (List I or II) No Yes
- ARCOS Reportable? No Yes 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 No
- Restricted to retail pharmacy only: No Yes
- Restricted to hospital, clinics, and physician offices only: No Yes
- Restricted from US territories? (explain in comments) No Yes

Comments:

SDS Hazard Classification

- Organic Corrosive
- Inorganic Oxidizer
- Steroid/Androgen 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 Yes
If Yes, is it managed with a pharmacy registry? No Yes
Website URL:

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

REMS: No Yes
REMS Program Manager Name: Phone:
Supplier Manages REMS registry exclusively: No Yes
Wholesale distributor support: No Yes
Provider Name: DEA #:
Site Enrollment Number assigned by Supplier: NCPDP#:
NPI #:

Comments

Registry: No Yes
Registry Program Contact Name: Phone:
Comments

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 1-866-827-3647
Is product returnable for credit: No Yes

URL/Link to returns policy: contact - customerservice@camberpharma.com

Special regulations or returns requirements for this product in certain states? No Yes
If so, which states? Other requirements? Comments?

MISCELLANEOUS NOTES and/or Image of Product Barcode:

