



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

Version 2021 Introduction Type: Post Launch Change Final Version Date: 6/24/2024

PRODUCT INFORMATION

Company Name: Camber Pharmaceuticals, Inc. Application: ANDA

Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 208213

Medical Device Class, if applicable:

DUNS: 11-856-3719

Proprietary Name (If Applicable) and Established Name: Roflumilast Tablets 250 mcg

Selling Unit NDC: 31722-676-32 Unit of Use NDC: CVX Code: UPC: 331722676328

UDI: MVX Code:

Description: Roflumilast Tablets 250 mcg

Active Ingredient(s): Roflumilast

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 phosphodiesterase-4 enzyme inhibitor

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):

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? No

Special returns requirements for this product? No

d. Store product (unit of sale) upright? No

Protect product (unit of sale) from light? No

e. Shelf life: 24 Months

Initial shelf life at launch (if different): Months

ADDITIONAL PRODUCT INFORMATION

The product is a legend device? No

if yes, enter class #

a product kit? No

if yes, list NDCs of component parts reverse numbered?

co-licensed? No

latex-free? Yes

preservative-free? Yes

correctional institution block? No

opioid? No

Cannabinoid? No

If Unit Dose, is item bar coded to unit dose for hospital scanning? Yes

If Unit Dose, indicate NDC here: 31722-676-31

Is the Product... Direct-Ship Only

Is the Product... Unit Dose

Orphan Drug Status

FDA Approval Status

Allergens Present: **Gluten, Wheat, Corn, Alcohol**

Country of Origin: **India**

Is this product covered under the Trade Agreements Act (TAA)? No

PRODUCT DESCRIPTION INFORMATION

Size: 20 Unit-dose tablets (2 x 10)

Strength: 250 mcg

Dosage Form: Tablet

Product Shape: Round, flat, bevel edged

Product Color: White to off white

Product Imprint: Debossed with 'H' on one side and 'T' on the other

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 Carton of 20 Unit-Dose Tablets

(Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity? Yes

If Yes, how many of which package type?

1 Each

Inner/ Carton/ Pack

Case

FOR GENERIC DRUG PRODUCTS

Authorized Generic *If Authorized Generic, other section fields are not applicable

I. Orange Book Rating: AB

II. Generic Equivalent to What Brand?: Daliresp

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?

(Write-in, e.g. 1 Vial)

Rx billing unit to pharmacy:

Each

Gram

Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? Yes

Is product exempt from DSCSA? No

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/exception/exemption for product? No

If yes, attach documentation from FDA.

GLN: 0331722498975

GCP:

If yes, was original product purchased direct from mfr?

Provide source manufacturer for repackaged product

ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Box/Carton/Bundle/ Inner Pack:	0.04	4.5	1	2	9	1
Case:	11.6	15	12	13	2340	231
Pallet:						

GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1		00331722676328	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	231		20331722676322	
<input type="checkbox"/> Pallet				

COST INFORMATION

Regular Cost:

Invoice Cost (WAC) (\$): \$50.00

As of date: 10/1/2023

WHOLESALE USE ONLY:

Vendor #:

Whsl. Code #:

Fineline Code:



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

Version 2021

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) No

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) No

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: 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#

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 by Supplier: NCPDP#:
 NPI #:

Comments

Registry: No

Registry Program Contact Name: Phone:
 Comments

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:

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:



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

Version 2021

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 <input type="checkbox"/> b. Autofax <input type="checkbox"/> c. Fax <input type="checkbox"/> d. Phone only <input type="checkbox"/> e. Supplier Web Site only <input type="checkbox"/> Minimum Order Quantity: <input type="text"/> Supplier's Customer Service Number: <input type="text"/> Contracted 3PL company / contact #: <input type="text"/> Name: <input type="text"/> Phone: <input type="text"/> Fax Number: <input type="text"/> Fax Number: <input type="text"/> Phone No.: <input type="text"/> Site Address: <input type="text"/>	Purchase order daily receipt cut off time by supplier Cut off time: <input type="text"/> Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days Ships same day for next day receipt: <input type="checkbox"/> Ships for second day receipt: <input type="checkbox"/> Ships regular ground for 3-10 days receipt: <input type="checkbox"/>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: <input type="text"/> Drop Ship service fee billed with each order: <input type="text"/> Drop Ship miscellaneous fees billed: <input type="text"/> Comments: <input type="text"/>	Overnight receipt available: <input type="checkbox"/> PO Receipt cut off time: <input type="text"/> Days of week overnight is available: <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday Priority Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Saturday Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="text"/> Overnight Fees apply: <input type="checkbox"/> Other fees apply: <input type="checkbox"/>
Class of Trade Restriction:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Restricted to retail pharmacy only: <input type="checkbox"/> Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> Restricted from US territories? (explain in comments) <input type="checkbox"/> Comments: <input type="text"/>	
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: <input type="text"/> Physician Name: <input type="text"/> Physician/Clinic Phone #: <input type="text"/> Physician State License #: <input type="text"/> Physician/Clinic DEA #: <input type="text"/> Physician/Clinic Specialty: <input type="text"/>	Contact # if product is received damaged: <input type="text"/> Is product returnable for credit: <input type="checkbox"/> URL/Link to returns policy: <input type="text"/> Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> If so, which states? Other requirements? Comments? <input type="text"/>
Miscellaneous Notes:	ADDITIONAL INFORMATION
<input type="text"/>	Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>