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

Version 2024 | Introduction Type: New Item | x Final Version | Date: 5/12/2026

PRODUCT INFORMATION

Company Name: Camber Pharmaceuticals, Inc.
Application: ANDA
Application Number for NDA/ANDA/BLA; PMA/510(k): 219850
NDA 505(b) Type: NOT APPLICABLE
Medical Device Class, if applicable:
DUNS: 11-856-3719
Proprietary Name (If Applicable) and Established Name: Buprenorphine and Naloxone Sublingual Film 12 mg/3 mg
Selling Unit NDC: 31722-482-30
Unit of Use NDC: 31722-482-30
UPC: 331722482301
UDI
CVX Code:
MVX Code:
Description: Buprenorphine and Naloxone Sublingual Film 12 mg/3 mg
Active Ingredient(s): Buprenorphine hydrochloride, USP and naloxone hydrochloride dihydrate, USP
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: Partial opioid agonist and opioid 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? *Yes
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: 30 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? No
co-licensed? No
latex-free? Yes
preservative-free? No
correctional institution block? No
opioid? Yes
Cannabinoid? No
If Unit Dose, is item bar coded to unit dose for hospital scanning?
If Unit Dose, indicate NDC here:

Is the Product… Direct-Ship Only
Is the Product… Unit of Use
Orphan Drug Status
FDA Approval Status
Allergens Present: Alcohol, Corn, Gluten, Sugar, Wheat
Country of Origin: USA
Is this product covered under the Trade Agreements Act (TAA)? Yes

PRODUCT DESCRIPTION INFORMATION

Size: 30 ct
Strength: 12 mg/3 mg
Dosage Form: Sublingual film
Product Shape: Rectangular
Product Color: Light orange to dark orange
Product Imprint: Imprinted with 'A12' on one side and plain on other side

ORDER INFORMATION

Unit of Sale
- Bottle
- x 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 30 Sublingual Films
(Write-in, e.g. 1 Box of 10 Vials)
Minimum order quantity? Yes
If Yes, how many of which package type?
30 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?: Suboxone

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?
(Write-in, e.g. 1 Vial)
HCPCS J-Code: J0575
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: 0843368117603
GCP:
If yes, was original product purchased direct from mfr?
Provide source manufacturer for repackaged product

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.) Depth	Width	Height	Volume (Cube)	Saleable # Pieces
Item/Each:	0.10	3.81	2.25	1.25	10.72	1
Box/Carton/Bundle/ Inner Pack:						
Case:	3.68	13.1	8.8	4.1	472.65	30
Pallet:						

GTIN AND HIBCC PRODUCT INFORMATION

	Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
x	Item/Each	N	1		00331722482301	00331722482301
	Box/Carton/Bundle/Inner Pack					
x	Case	N	30		10331722482308	
	Pallet					

COST INFORMATION

Regular Cost
Invoice Cost (WAC) ($): $120.00
As of date: 4/17/2026

WHOLESALER USE ONLY:

Vendor #:
Whsl. Code #:
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:

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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)	No
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)	No
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#

SDS Hazard Classification

- [x] 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?	Yes
If Yes, is it managed with a pharmacy registry?	No
Website URL:	www.BTODREMS.com
Med Guide Required	Yes
Limited Distribution Requirement	No
Comments / Details: (For example, iPledge program?)	Buprenorphine Transmucosal Products for Opioid Dependence (BTOD) Shared Systems REMS Program

REMS: Yes

REMS Program Manager Name:	Syneos Health	Phone:	855-223-3922
Supplier Manages REMS registry exclusively:	No		
Wholesale distributor support:	No		
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?	Yes	Controlled Substance Code	9064
Controlled by State(s)?	Yes	Listed Chemical (List I or II)	No
ARCOS Reportable?	Yes	If yes, indicate which:	
Schedule No.	3	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:

*Storage of this product must abide by the federally mandated DEA requirements outlined in 21 CFR Part 1301.72.

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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

Purchase orders may be accepted by:

a. EDI
b. Autofax — Fax Number:
c. Fax — Fax Number:
d. Phone only — Phone No.:
e. Supplier Web Site only — Site Address:

Minimum Order Quantity:
Supplier's Customer Service Number:
Contracted 3PL company / contact #: Name:
Phone:

Standard Order Receipt and Processing

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?