



# 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:  Application:

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

Medical Device Class, if applicable:

DUNS:

Proprietary Name (If Applicable) and Established Name:

Selling Unit NDC:  Unit of Use NDC:  UPC:

UDI:  CVX Code:  MVX Code:

Description:

Active Ingredient(s):

URL for Additional Product Information:

Address:  Address 2:

City:  State:  Zip:

Key Contact:  Email:

Phone Number:  Fax:

Product Therapeutic Classification:

## SPECIAL HANDLING AND STORAGE REQUIREMENTS\*

a. Temperature – Indicate the USP temperature range for this product.  
 Temperature Range:

Other Temperature Range Requirement (write in):

Notes:

Is this product to be shipped to customers on ice?

Is this product to be shipped to customers on dry ice?

b. Contact for temperature excursion questions:  
 Name:   
 Number:   
 Group E-mail:

c. Special regulations for product in any states?  
 Special returns requirements for this product?

d. Store product (unit of sale) upright?

Protect product (unit of sale) from light?

e. Shelf life:  
 Initial shelf life at launch (if different):  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="120 ct"/>	
if yes, enter class # a product kit? <input type="text" value="No"/>	Is the Product... Unit of Use <input type="text"/>	Strength: <input type="text" value="200 mg"/>	
if yes, list NDCs of component parts reverse numbered? <input type="text"/>	Orphan Drug Status <input type="text"/>	Dosage Form: <input type="text" value="Film-coated tablet"/>	
co-licensed? <input type="text" value="No"/>	FDA Approval Status <input type="text"/>	Product Shape: <input type="text" value="Oval, biconvex"/>	
latex-free? <input type="text" value="Yes"/>	Allergens Present <input type="text" value="Dairy, Lactose"/>	Product Color: <input type="text" value="Pink"/>	
preservative-free? <input type="text" value="Yes"/>	Country of Origin <input type="text" value="India"/>	Product Imprint: <input type="text" value="Debossed 'H' on one side with a score line and 'R' and '7' separated by score line on the other side."/>	
correctional institution block? <input type="text" value="No"/>	Is this product covered under the Trade Agreements Act (TAA)? <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"/>			

## ORDER INFORMATION

Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	<input type="text" value="1 Bottle of 120 Tablets"/>
<input type="checkbox"/> Box/Carton	<input type="text" value="(Write-in, e.g. 1 Box of 10 Vials)"/>
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	Minimum order quantity? <input type="text" value="Yes"/>
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	
<input type="checkbox"/> Vial Powder Sgl	If Yes, how many of which package type?
<input type="checkbox"/> Vial Powder Multi	<input type="text" value="24"/> Each
<input type="checkbox"/> Other: Write In	<input type="text" value="Inner/ Carton/Pack"/>
	<input type="text" value="Case"/>

## FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating:   Authorized Generic \*If Authorized Generic, other section fields are not applicable

II. Generic Equivalent to What Brand?:

## PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?

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

Rx billing unit to pharmacy:

## DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?

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/exception/exemption for product?

If yes, attach documentation from FDA.

GLN:

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:	0.3	2.25	2.25	4.5	22.78	1
Case:	7.75	14	9.5	5	665.00	24
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		00331722598125	00331722598125
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	24		30331722598126	
<input type="checkbox"/> Pallet				

## COST INFORMATION

Regular Cost

Invoice Cost (WAC) (\$)

As of date:

WHOLESALE USE ONLY:  
 Vendor #:   
 Whsl. Code #:   
 Finline Code:



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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 by State(s)?  No  Yes
- ARCOS Reportable?  No  Yes
- Schedule No.
- Controlled Substance Code
- Listed Chemical (List I or II)  No  Yes
- If yes, indicate which:
- Is it a scheduled listed chemical product?:  No  Yes

### 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:



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