



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

Version 2024 Introduction Type:  New Item  Final Version Date: 10/10/2024

## PRODUCT INFORMATION

**Company Name:** Camber Pharmaceuticals, Inc. **Application:** ANDA  
**Application Number for NDA/ANDA/BLA; PMA/510(k):** 217166 **NDA 505(b) Type:** NOT APPLICABLE  
**Medical Device Class, if applicable:** \_\_\_\_\_  
**DUNS:** 11-856-3719  
**Proprietary Name (If Applicable) and Established Name:** Ketorolac Tromethamine Injection, USP 15 mg/mL (Single-Dose Vials)  
**Selling Unit NDC:** 31722-305-25 **Unit of Use NDC:** \_\_\_\_\_ **UPC:** 331722305259  
**UDI:** \_\_\_\_\_ **CVX Code:** \_\_\_\_\_ **MXV Code:** \_\_\_\_\_  
**Description:** Ketorolac Tromethamine Injection, USP 15 mg/mL (Single-Dose Vials)  
**Active Ingredient(s):** Ketorolac tromethamine, USP  
**URL for Additional Product Information:** [www.camberpharma.com](http://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](mailto:customerservice@camberpharma.com)  
**Phone Number:** 1-866-827-3647 **Fax:** 732-562-8788  
**Product Therapeutic Classification:** Nonsteroidal anti-inflammatory drug (NSAID)

## 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?  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](mailto:somaraju@heterousa.com)  
**c. Special regulations for product in any states?**  
 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:** 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:   No  
**Is the Product... Direct-Ship Only**   
**Is the Product... Unit Dose**   
**Orphan Drug Status**   
**FDA Approval Status** \_\_\_\_\_  
**Allergens Present** \_\_\_\_\_  
**Country of Origin**   
 Is this product covered under the Trade Agreements Act (TAA)?  No

## PRODUCT DESCRIPTION INFORMATION

**Size:** 25 x 1 mL single-dose, flip top vials  
**Strength:** 15 mg/mL per single-dose vial  
**Dosage Form:** Sterile, clear solution  
**Product Shape:** N/A  
**Product Color:** Slightly yellow  
**Product Imprint:** N/A

## 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?**   
 (Write-in, e.g. 1 Box of 10 Vials)  
**Minimum order quantity?**  Yes  
**If Yes, how many of which package type?**  
 Each  
 Inner/Carton/Pack  
 Case

## FOR GENERIC DRUG PRODUCTS

**I. Orange Book Rating:**   
**II. Generic Equivalent to What Brand?:**   
 Authorized Generic \*If Authorized Generic, other section fields are not applicable

## PHARMACY ORDER / BILL UNIT

**Rec. sell unit to customer?** \_\_\_\_\_  
 (Write-in, e.g. 1 Vial)  
**HCPCS J-Code:**   
**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:**   
**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:	0.44	3.4	3.4	2.21	25.55	1
Case:	8.95	11	11	5.5	665.5	18
Pallet:						

## GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	N	1		00331722305259	
<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack					
<input checked="" type="checkbox"/> Case	N	18		20331722305253	
<input type="checkbox"/> Pallet					

## COST INFORMATION

**Regular Cost** \_\_\_\_\_  
**Invoice Cost (WAC) (\$)**   
 As of date:   
**WHOLESALE USE ONLY:**  
**Vendor #:** \_\_\_\_\_  
**Whsl. Code #:** \_\_\_\_\_  
**Fineline 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  No
- Passenger & Cargo  No

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  No

NFPA Storage Level:

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?  No

Website URL:

Med Guide Required  No

Limited Distribution Requirement  No

Comments / Details: (For example, iPledge program?)

REMS:  No

REMS Program Manager Name:

Phone:

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

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:  1-866-827-3647

Is product returnable for credit:  Yes  No

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)

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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"/></p> <p>c. Fax <input type="checkbox"/></p> <p>d. Phone only <input type="checkbox"/></p> <p>e. Supplier Web Site only <input type="checkbox"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/></p> <p>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Phone No.: <input type="text"/></p> <p>Site Address: <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>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
<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 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</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><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: <input type="text"/></p> <p>Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>
Class of Trade Restriction:	
<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>	
Other Data Information Required to Process PO:	Return Instructions
<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>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>
Miscellaneous Notes:	ADDITIONAL INFORMATION
<p><input type="text"/></p>	<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>