

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

						Introduction Type:	New Item	]	x Final Version			Date:	10/17	7/2025
			PRODUCT INFORMA	TION					SPECIAL HANI	DLING AND STOR	AGE REQUIF	EMENTS*		
Company Name:	Camber Pharmace	euticals, Inc.				Application:	ANDA	a. Temperatu	re - Indicate the USP tempe	rature range for t	nis product.			
Application Number for NDA/AN			5			NDA 505(b) Type:	NOT APPLICABLE	1		Cold – between 2		- 46° F)		
Medical Device Class, if applical								Ţ	, ,			-		
DUNS:	11-856-3719								Other Temperature Range F	Requirement				
Proprietary Name (If Applicable) a		me: Indome	ethacin Suppositories, USP					Ţ	(write in)					
Selling Unit NDC:	31722-051-31		Unit of Use NDC	:			22051316	I	Notes		*To be shipped	o customers usi	ng proper cold st	torage shipping
UDI			CVX Code:			MVX Code:					methods (e.g. C	old Packs, Cold	Storage Trucks)	
Description:	Indomethacin Sup	positories, USP 50 m	ng					T	Is this product to be shipped	to customers on ic	e?		No	
	, ,		<u> </u>						Is this product to be shipped				No	
Active Ingredient(s):		Indomethacin, USP						1						
								b. Contact for	r temperature excursion que	estions:				
URL for Additional Product Inforn		www.camberpharma	a.com						Name:		Soma Raju			
Address:	800 Centennial Av	e, Suite 1			04-4	Address 2:	100054	-	Number:		732-529-042			
City:	Piscataway Customer Service				State: Email:		08854	-	Group E-mail:		somaraju@h	eterousa.con	<u>1</u>	
Key Contact: Phone Number:	1-866-827-3647				Fax:	rational rat	<u>berpharma.com</u>	a Special rea	ulations for product in any	ototoo?			No	1
Product Therapeutic Classificatio		Non storoidal anti in	nflamatory indole derivative	drug (NCAID)	l ux.	132-302-0100		c. Special reg					No	
Product Therapeutic Classificatio	m:	Non-steroidal anti-in	mamatory indole derivative	ulug (NSAID)					Special returns requirements	s for this product?			INO	I
	ADDITIO	ONAL PRODUCT INF	FORMATION			PPODUCT DESC	RIPTION INFORMATION	d Store produ	uet (unit of cale) unright?				No	1
The new decades 2	ADDITIO	SKAL PRODUCT IN		Diseast Other C	Name to a	- FRODUCT DESCI	AI HON IN ORMATION	a. Store prodi	uct (unit of sale) upright?	L-) 6 12 - 1-0				1
The product is?		NI.	Is the Product	Direct-Ship O	лпу		20 et	a Chalfill	Protect product (unit of sa	ie) from light?			No 24	Mantha
a legend device? if yes, enter class #		No	Is the Product Orphan Drug Status	Unit Dose		Size:	30 ct	e. Shelf life:	Initial shelf life at launch (i	f difforont\:			24	Months Months
a product kit?		No	Orphan Drug Status				50 mg		illiuai sileli ille at laulicii (i	i dillerentj.				WIOTILIS
if yes, list NDCs of		INO	FDA Approval Status			Strength:	30 mg			ORDER INFORM	ATION			
component parts			. Dittippioral Galac				Suppository packed in							
reverse numbered?		No				Dosage Form:	Alu/PE molds		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						Bottle		1 Box of 30 S	Suppositories		
latex-free?		Yes		Soy		Product Shape:	Bullet		x Box/Carton		(Write-in, e.	. 1 Box of 10	Vials)	
preservative-free?		Yes		Joy		Froduct Snape.			Ampule					
correctional institution block?		No				Product Color:	White to off white		Glass		Minimum or	der quantity	?	Yes
opioid?		No							Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint:	N/A		Vial Liquid Sgl		W.V 1			
If Unit Dose, is item bar coded to unhospital scanning?		No	Is this product covered	dan tha					Vial Liquid Multi Vial Powder Sql			nany or wni Each	ch package t	:ype?
If Unit Dose, indicate NDC here:		31722-051-32	Trade Agreements Act (		No				Vial Powder Sgi Vial Powder Multi		12	Each Inner/Carton	/Pack	
II Offit Bose, indicate NBO ficie.		01722-001-02	Trado / igroomonio / ior (	., ., .	140				Other: Write In			Case	1 dok	
			FOR GENERIC DRUG PF	PODUCTS				1						
					Au	uthorized Generic *If Au	thorized Generic, other		PH.	ARMACY ORDER	/ BILL UNIT			
I Orange Book Rating	AB				Au		uthorized Generic, other on fields are not applicable	Rec sell unit		ARMACY ORDER		it to pharms	CV.	
I. Orange Book Rating:	AB	Indocin			Au			Rec. sell unit		ARMACY ORDER	/ BILL UNIT		ıcy:	
I. Orange Book Rating: II. Generic Equivalent to What Bra		Indocin			Au				to customer?	ARMACY ORDER		Each	icy:	
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### **Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)**

#### Version 2024

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL	HAZARD CLASSIFICATION and TRANSPORTATION				
Is this product (check all that apply):  a. Cytotoxic?  b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	SDS Hazard Classification				
Is the product a CA Prop 65 carcinogen?  Is the product a CA Prop 65 reproductive toxicant?  Does the product label bear a CA Prop 65 warning?  No					
c. Contact Hazard? d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) e. Does the product contain DEHP?	identify NFPA Storage Level: NFPA Storage Level:				
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	Is the product a NIOSH hazardous drug?  If yes, indicate which:				
c. DOT Hazard Class d. Packing Group	Hazardous Waste Identification				
e. Inhalation Hazard?  Is this product regulated for shipment by IATA?  No					
(if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group	Is there a REMS on this product?  If Yes, is it managed with a pharmacy registry?  Website URL:				
e. Inhalation Hazard?  Is the product restricted for air shipment? If so, indicate restriction:  Passenger Cargo Passenger & Cargo	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)				
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)	REMS:  REMS Program Manager Name:  Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier:  No Phone:  DEA #: NCPDP#: NPI #:				
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);	Comments				
SP# ADD'L STORAGE INFORMATION	Registry:  Registry Program Contact Name:  Comments  No  Phone:				
Is the Product	Comments				
Controlled Substance? Controlled Substance Code Controlled by State(s)? ARCOS Reportable? Schedule No.  No If yes, indicate which: Is it a scheduled listed chemical product?:  CLASS OF TRADE RESTRICTION:	Contact tel. # if product received damaged: 1-866-827-3647				
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Ye					
Restricted to retail pharmacy only:  No  No  No  No  No  No  No  No  No  N					
Restricted to hospital, clinics, and physician offices only:  Restricted from US territories? (explain in comments)  No	Special regulations or returns requirements for this product in certain states?  If so, which states? Other requirements? Comments?				
Comments:	n so, miori sales: Otro requiencino.				
MISGELL	NEOUS NOTES and/or Image of Product Barcode:				



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

#### Version 2024

#### FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Purchase order ally receipt cut off time by supplier  a. EDI b. Autofax C. Fax Fax Number: C. Fax d. Phone only Phone only Supplier Veb Sile only Supplier Veb S	Order Method	for Designated Drop Ship Product	Standard Order Receipt and Processing
b. Autofax c. Fax d. Phone only e. Supplier Web Site only e. Supplier Web Site only supplier Subserver Service Number: Contracted 3PL company / contact #: Name: Phone Phone Phone Phone Phone Site Address Ships aame day for next day receipt: Ships regular ground for 3-10 days receipt: S	Purchase orders may be accepted by:		Purchase order daily receipt cut off time by supplier
d. Phone only e. Supplier Web Site only Site Address: Supplier Soustomer Service Number: Contracted 3PL company / contact # Name: Phone No.  Expedited freight Charges or Other Designated Drop Ship Fees:  Expedited freight fees billed with each order: Drop Ship service fee billed: Drop Ship service fee billed with each order: Drop Ship service fee billed: Drop Ship service fee billed: Drop Ship service fee billed: Drop Ship service fee billed with each order: Drop Ship service fee billed: Drop Ship ser	a. EDI		Cut off time:
d. Phone only e. Suppler Web Site only Site Address:  Ships same day for next day receipt: Ships for second day receipt wallabe: Drownight for ships for ceipt: Ships for second day receipt wallabe: Drownight for ceipt valiable: Dry Receipt differs Dry Receipt day receipt wallabe: Dry Receip			
e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL. company / contact #: Name: Phone:  Expedited Freight Carlanges or Other Designated Drop Ship Fees:  Expedited Freight Carlanges or Other Designated Drop Ship Fees:  Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Drop Ship miscellaneous fees bi			Shipping lead time of PO: Hours Days
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