

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

Version 2024						Introduction Ty	pe: New Item		x	Final Version			Date:	6/27/	/2025
			PRODUCT INFORMAT	TION						SPECIAL HAN	DLING AND STOR	AGE REQUIF	REMENTS*		
Company Name:	Camber Pharmac					Application		a. Tempera	ture – Indic	ate the USP tempe	erature range for th				
Application Number for NDA/AN		O(k): 219160				NDA 505(b) Type:	NOT APPLICABLE		Tempera	ature Range	Controlled Room -	between 20	and 25 C (68	° – 77° F)	
Medical Device Class, if applical															
DUNS: Proprietary Name (If Applicable) a	11-856-3719	- December	pride Tablets 2 mg							emperature Range F rite in)		(between 59)		ween 15°C to	30°C
Selling Unit NDC:	31722-392-30	ame. Flucato	Unit of Use NDC:		31722-392-30	UPC: 3	331722392303		Notes	ite iii)		(between 55	1 10 00 1)		
UDI			CVX Code:			MVX Code:			110100						
Description: Prucalopride Tablets 2 mg Is this product to be shipped to customers on ice? No									1						
2000p											d to customers on di			No	
Active Ingredient(s):		Prucalopride succina	te												4
								b. Contact		ture excursion qu		Soma Raju			
URL for Additional Product Inform Address:	800 Centennial A	www.camberpharma.	com		1	Address 2:			Name: Number			732-529-042	3		
City:	Piscataway	ive, oute 1			State:		Zip : 08854		Group E			somaraju@h		n	
Key Contact:	Customer Service	е			Email:		camberpharma.com				'				
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special r	regulations 1	for product in any	states?			No	
Product Therapeutic Classificatio	n:	Serotonin-4 (5-HT ₄) r	eceptor agonist						Special r	returns requirement	ts for this product?			No	
	ADDIT	IONAL PRODUCT INF	ODMATION			PRODUCT DE	ESCRIPTION INFORMATION			- f l -)				NI.	1
	ADDITI	IONAL PRODUCT INF		D: 101: 6		PRODUCT DE	ESCRIPTION INFORMATION	d. Store pro		of sale) upright?				No	
The product is?		N.	Is the Product	Direct-Ship C Unit of Use	only		30 ct	e. Shelf life		product (unit of sa	ale) from light?			No 24	Mantha
a legend device? if yes, enter class #		No	Orphan Drug Status	Offic of Ose		Size:	30 Cl	e. Shell life		nelf life at launch (if different):			24	Months Months
a product kit?		No	Orphan Brug Gatas			04	2 mg		illidai Si	icii ilic at laalicii (ii uiiiciciiig.				Months
if yes, list NDCs of			FDA Approval Status			Strength:					ORDER INFORM	ATION			
component parts						Dosage Form:	Film-coated tablet								
reverse numbered? co-licensed?		No	Allergens Present						Unit of S	Sale Bottle		What is the 1 Bottle of 30		unit?	
latex-free?		No Yes					Round biconvex		X	Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		Yes	Dairy, Lact	ose, Casein		Product Shape	e:			Ampule		(**************************************	g. 1 Dox of 1	, , , , , , ,	
correctional institution block?		No				Product Color	Yellow			Glass		Minimum or	der quantity	?	Yes
opioid?		No					Debossed with '77' on one si			Tube					
Cannabinoid? If Unit Dose, is item bar coded to u	init doos for	No	Country of Origin	India		Product Imprir	nt: Debossed with '77' on one side	ie		Vial Liquid Sgl Vial Liquid Multi		If Voc. how	many of whi	ich package t	tuno?
hospital scanning?	init dose for		Is this product covered u	nder the						Vial Powder Sgl			Each	сп раскаде і	type r
If Unit Dose, indicate NDC here:			Trade Agreements Act (T		No					Vial Powder Multi			Inner/Carton	ı/Pack	
										Other: Write In			Case		
			FOR GENERIC DRUG PRO	ODUCTS											
						thorized Generic *	If Authorized Generic, other			PH	IARMACY ORDER	/ BILL LINIT			
I. Orange Book Rating:	AB			_	Au		section fields are not applicab	le Boo cell u	nit to custon			Rx billing ur	-14 4		
II. Generic Equivalent to What Bra		Motegrity						ixec. sell ul	int to custon	ilei :	1	KX billing ui	Each	icy.	
						(Write-in, e			-		Gram				
		DRUG SUPPLY	CHAIN SECURITY ACT (DSCSA) INFOR	RMATION			HCPCS J-C	Code:				Milliliter		
Does supplier meet DSCSA defini	tion of manufactu	ror?	Yes	7	GLN:	0331722498975				ITEN	AND PACKING IN	FORMATION	J		
Is product exempt from DSCSA?			No		02	0001122100010							•		
If yes, select exemption:					GCP:						Dimensio	ons (US msm	its.)	Volume	Saleable #
Other exemption - Write in:										Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No Yes	_		iginal product purch	nased	Item/Each:		0.07	1.45	1.45	2.32	4.88	1
Is product sold by manufacturer's Has FDA granted waiver/exception			No	-	direct from m		repackaged product	Box/Carton	/Rundle/						
If yes, attach documentation from		Toductr	140		Flovide Soul	ce manufacturer for	repackageu product	Inner Pack							
l								Case:		2.1	9	6.5	4	234.00	24
		GTIN	AND HIBCC PRODUCT IN	FORMATION						2.1	Ů	0.0	-	204.00	2-7
Saleable Unit of Measure	RFID tag(Y/N)	Saleable	HIBCC		GTI	N-14	Unit of Use GTIN-14	Pallet:							
Saleable of the of Weasure	IN ID tag(1/14)	Quantity	TIIDOO		011	14-14	01111 01 036 01114-14								
x Item/Each	N	1			003	31722392303	00331722392303								
Box/Carton/Bundle/Inner Pack									cos	T INFORMATION		\	WHOLESALI	ER USE ONL	.Y:
X Case	N	24			203	31722392307		-				Vande: #			
Pallet					-			Regular Co	st (WAC) (\$)		\$120.34	Vendor #: Whsl. Code	#-		
								voice cos	o. (••Ao) (\$)	,	\$120.34	Fineline Code			
								As of date:		6/25/2025					
L			A#	TA OUE = T / = =	.0) :		NOEDT LABEL AND BUILT	05.0000::07.5::	NA OIL: C	10400055					
*Please provide any additional inf	ormation on page		Aπach copy of SAFETY DA	IA SHEET (SE	اک) or non haza		NSERT, LABEL AND PHOTO esignated Drop Ship Only.	OF PRODUCT PAC	KAGING and Signatur						
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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? b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	No	SC	S 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?	x Organic Inorganic Steroid/Androgen	Corrosive Oxidizer Contact Hazard				
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?	No No	Does the product have an Aerosol class? If yes, 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	No	Is the product a NIOSH hazardous drug? If yes, indicate which:	No			
c. DOT Hazard Class d. Packing Group		Haza EPA Hazardous Waste Code:	rdous Waste Identification	Waste Characteristics		
e. Inhalation Hazard? Is this product regulated for shipment by IATA?	No	EFA Hazardous Waste Code.		Waste Characteristics		
(if yes, answer a-e below and provide SDS)		REMS o	r REGISTRY RESTRICTIONS			
a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?		Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:	No			
Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo	No	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)	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)		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#		Registry: Registry Program Contact Name:	No	Phone:		
ADD'L STORAGE INFORMATION		Comments		Thoric.		
Is the Product Controlled Substance? Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II)	No	RI	ETURN INSTRUCTIONS			
ARCOS Reportable? Schedule No. If yes, indicate which: Is it a scheduled listed chemical product?:	No	Contact tel. # if product received damaged: Is product returnable for credit:	1-866-827-3647 Yes			
CLASS OF TRADE RESTRICTION:		URL/Link to returns policy:				
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Yes	contact - customerse	rvice@camberpharma.com			
Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only:	No No	Special regulations or returns requirements for this product in certain states?				
Restricted from US territories? (explain in comments) Comments:	No	If so, which states? Other requirements? Comments?				
MI	SCELLANEC	US 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.

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:				
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