

Standard Pharmaceutical Product Information (Rx Product Only)

Part	© August 2014 Introduction Type: New Item									Final Version			Date:			
Application number for NUMANDAMA ARTINOS PRACTICAL PROCESSOR 1990 19	PRODUCT INFORMATION									SPECIAL HANDLING AND STORAGE REQUIREMENTS*						
Application Number for MCAMMORIAN Bright (MCATS) (MCAT	Company Name: Camber Pharmaceuticals Application: ANDA															
Power Powe	Application Number for ND				202682	202682										
Montanger Description Montanger Description Desc	DUNS:	826774775							Other Temperature Range Requirement							
Contract		etine Hydrochloride Capsules, 25n	ng 30ct	oct												
Description: Desc	Selling Unit NDC: 31722-716-30 Individual Unit NDC:					UPC: 331722716307									•'	
Accordance in Important in the Control Contr	UDI CVX Code:				MVX Code:			Is this product to be shipped to customers on ice? No								
Note:	Description: Capsule; Cap: Opaque blue; Body: White opaque; I' on cap and '107' on body Is this product to be shipped to customers on dry ice? No											No				
Note:																
Ministrate Min	Active Ingredient(s):		Atomoxetine													
Comparison Com	LIPI for Additional Braduat I	nformation	www.cambernharma.co	am .					41							
Control Description Product The product Closer Product) iii	Address 2:											
Product			140		State:				1	-maii.		oomaraja@i	101010404.00	·		
## ADDITIONAL PRODUCT INFORMATION In the Product.		Customer Service			Email:					c. Special regulations for product in any states?						
ADDITIONAL PRODUCT INFORMATION	Phone Number:	732-529-0430			Fax:	Fax: 732-562-8788			Special returns requirements for this product? No							
PRODUCT DESCRIPTION INFORMATION PRODUCT DESCRIPTION INFORMATION Product red find refer of the product of the find of service of the product of the find of the product of the produc	Product Therapeutic Classifi	ication:								<u> </u>						
### Support devices numbered? No																
Size	ADDITIONA	AL PRODUCT INFORM	IATION		F	PRODUCT DESCRIPTION INFORMATION				Protect product (unit of sale) from light?					<u>.</u>	
Concession					<u></u>									24		
Serious Seri				.	Size:	Size: 30			Initial shelf life at launch (if different):					Months		
is the Product Simple Product Shape Data Solid				:					ORDER INFORMATION							
11 Unit Does No. 12 Unit Does (Dr. Country of Origin 15 Unit Doe				•	Strength:	25 m	g			U	KDEK INI OI	MATION				
If Unit Dose, is item bar coded to unit dose for hospital scanning? No If Unit Dose NDC, Indicate NDC here. Country of Origin In this product Colors: In this product covered under the Trade Agreements Act (TAA)? No FOR GENERIC DRUG PRODUCTS FOR GENERIC DRUG				•			- · · ·		Unit of S	Sale		What is the	NDC selling	unit?		
True Does NOT, Grided NIO Prec. Gapsulo				•	Dosage Form	i: Oral	Solid					1 Bottle of 3	0 Capsules			
FOR GENERIC DRUG PRODUCTS Authorized Generic offer section fields are indisplicable feels are indisplicable are produced to purchased direct product purchased direct packaged? For GENERIC DRUG PRODUCT PRODUC	If Unit Dose, is item har coded to unit dose for hospital cooping?											(Write-in, e.	g. 1 Box of 1	0 Vials)		
Country of Origin Is this product covered under the Trade Agreements Act (TAA)/ Is this product covered under the Trade Agreements Act (TAA)/ Is this product covered under the Trade Agreements Act (TAA)/ Is this product covered under the Trade Agreements Act (TAA)/ Is this product covered under the Trade Agreements Act (TAA)/ Is the product covered under the Trade Agreements Act (TAA)/ Is the product covered under the Trade Agreements Act (TAA)/ Is the product covered under the Trade Agreements Act (TAA)/ Is the product covered under the Trade Agreements Act (TAA)/ Is the product covered under the Trade Agreements Act (TAA)/ Is the product covered under the Trade Agreements Act (TAA)/ Is the product covered under the Trade Agreements Act (TAA)/ Is the product covered under the Trade Agreements Act (TAA)/ Is the product covered under the Trade Agreements Act (TAA)/ Is the product covered under the Trade Agreements Act (TAA)/ Is the product covered under the Trade Agreements Act (TAA)/ Is the product covered under the Trade Agreements Act (TAA)/ Is the product covered under the Trade Agreements Act (TAA)/ Is the product twint and the product over the product ov	NO NO					Product Shape: Capsule								_		
Second Content of Co	If Unit Dose NDC, indicate N		·						Minimum o	rder quantity	/?	Yes				
Is this product covered under the Trade Agreements Act (TAA)? No Product Imprint: Fon cap and 107 on body Produc																
FOR CENERIC DRUG PRODUCTS Carge Book Rating: AB											If Yes. how	many of wh	ich package	type?		
Authorized Generic, Other section fields are not applicable Straterra	is this product covered under the Trade Agreements Act (TAA)? No			Product Impr	Product Imprint: If on cap and "107" on body			Vial Powder Sql 24 Each								
Authorized Generic Authorized Generic The Authorized Generic Th								JI					/Pack			
Authorized Generic Til Authorized Generic	EOR CENERIC DRIVE BRODUCTS									Other: Write In	1		Case			
1. Grange Book Rating: AE	FOR CENERIO SINGET ROSSOTS															
Continue Part Part Continue Part Continue Part Part Continue Part Part Continue Part Part Continue Part Pa					Auth	orized Generic	*If Authorize	ed Generic, other section	PHARMACY ORDER / BILL UNIT							
Strateria Stra	I. Orange Book Rating: AB				fields are not applicable			Rec. sell unit to customer?			Rx billing unit to pharmacy:					
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	II. Generic Equivalent to What Brand?: Straterra											Each	-			
Description Section	ADDIO AUDITY OF AUDITY AT THE AUTITY OF AUDITY AT THE AUTITY OF AUDITY AT THE AUTITY OF AUDITY AT THE AUDITY AUDITY AT THE AUDITY AUDITY AT THE AUDITY AUDITY AUDITY AND THE AUDITY AUDITY AT THE AUDITY AUDI								(Write-in, e.g. 1 Vial)							
S product exempt from DSCSA? No						Milliliter										
Sepreduct exemption:	Does supplier meet DSCSA of	definition of manufac	turer?	Yes	GLN:	03317220000	000		1	ITEM AN	ND PACKING	INFORMAT	ION			
Case Carton: Cost No	Is product exempt from DSC	SA?		No												
No										Weight Lbs.					# Pieces:	
Seproduct sold by manufacturer's exclusive distributor? No from mfr?				Ni					I		Depth	Height	Width	(Cube)		
Ras FDA granted waiver/exception/exemption for product? No If yes, attach documentation from FDA.		urar'a avaluaiva diatri	ihutor?			nal product pur	chased direct		Item:	0.02	1.51	2.34	1.51		1	
Inner Pack:						cumentation fro	om FDA		Box/Carton/Bundle/							
Saleable Cost NFORMATION Saleable Cost (WAC) (\$) Sederal Excise Tax Per Unit of Sale Saleable	That I be granted warver/exec	eption/exemption for			ii yes, attaeii aoc	ounicination ire	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,									
Level e Unit Country GTIN-14 O0331722716307 UPC: Case: UPC: Case: Country				GTIN PRODUCT INFORMATION	N				Case:	1 31	0.646	3.78	6.496		24	
Serialized? Yes X Item Sew/Carton/Bundle/Inner Pack X 2D Linear T 1 1 1 1 1 1 1 1 1										1.51	3.040	3.70	0.430		24	
If not, when? Items aggregated? Yes X Case X Z D Linear Z D D D D D D D D D D D D D D D D D D	01-140	V							Pallet:						225	
Items aggregated? Yes		res	т ⊢^					00331722710307	IIPC:	Caso.						
Pallet		Yes	<u> </u>					20331722716301								
Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE. Regular Cost Wacoust Wendor #: Whsl. Code #: Federal Excise Tax Per Unit of Sale As of date: Fineline Code: Whsl. Code #: Fineline Code: Whsl						Linear										
Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE. Regular Cost Vendor #: Vendor #: Invoice Cost (WAC) (\$) \$55.00 Whsl. Code #: Federal Excise Tax Per Unit of Sale As of date: Fineline Code: Fineline									COST	INFORMATION			WHOLESAL	ER USE ONL	.Y:	
Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.									Barrelon Coot			Vandau#	j			
Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.											\$55.00		#:			
As of date: Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.						Lindell					ψ33.00					
]				
				Attach copy of SAFETY DATA SHI	EET (SDS) or non haz				ODUCT PACKAGING and I	BARCODE.						



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION Is this product (check all that apply): a. Cytotoxic? SDS Hazard Classification No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Organic Is the product a CA Prop 65 carcinogen? No х Corrosive Is the product a CA Prop 65 reproductive toxicant? Oxidizer No Inorganic Does the product label bear a CA Prop 65 warning? No Steroid/Androgen Contact Hazard c Contact Hazard? Nο Aerosol Class; Identify NFPA Storage Level: d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) Is the product a NIOSH hazardous drug? e. Does the product contain DEHP? No If yes, indicate which: Is this product regulated for shipment by DOT or IATA? No (if yes, answer a-e below and provide SDS) a. UN/Identification Number Hazardous Waste Identification b. Proper Shipping Name c. DOT Hazard Class EPA Hazardous Waste Code: d. Packing Group e. Inhalation Hazard? No REMS or REGISTRY RESTRICTIONS Is the product restricted for air shipment? If so, indicate restriction: Passenger Is there a REMS on this product? No Cargo If Yes, is it managed with a pharmacy registry? Passenger & Cargo Website URL: Is this a reportable quantity? RQ Threshold: Comments / Details: (For example, iPledge program?) Is this a marine pollutant? No Is this product shipped utilizing an authorized DOT exception or Special Permit? (if yes, identify method below) REMS: Limited Quantity REMS Program Manager Name: Phone: Consumer Commodity, ORM-D Supplier Manages REMS registry exclusively: Small Quantity (49 CFR 173.4) Wholesale distributor support: Special Permit: DOT-SP Provider Name: Special Provision (listed in Column 7 of 49 CFR 172.101); Site Enrollment Number assigned DEA #: by Supplier: PCPDP #: NPI#: ADD'L STORAGE INFORMATION Is the Product... Comments Controlled Substance? No Controlled by State(s)? No Registry: ARCOS Reportable? No Registry Program Contact Name: Schedule No. (inc. N for non-narcotic) Comments Controlled Substance Code Listed Chemical (List I or II) No RETURN INSTRUCTIONS If yes, indicate which: 732-529-0430 Is it a scheduled listed chemical product?: No Contact tel. # if product received damaged: **CLASS OF TRADE RESTRICTION:** Is product returnable for credit: contact - customerservice@camberpharma.com No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes URL/Link to returns policy: No Restricted to retail pharmacy only: No Special regulations or returns requirements for this product in certain states? Restricted to hospital, clinics, and physician offices only: No If so, which states? Other requirements? Comments? Restricted from US territories? (explain in comments) No Comments: MISCELLANEOUS NOTES and/or Image of Product Barcode:



Standard Pharmaceutical Product Information (Page 3)

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
Purchase orders may be accepted by: a. EDI	Purchase order daily receipt cut off time by supplier Cut off time: Eastern
b. Autofax c. Fax d. Phone only Fax Number: Phone No.:	Shipping lead time of PO: Hours Days
e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	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:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:	Overnight receipt available:
Drop Ship service fee billed with each order:	PO Receipt cut off time: Eastern
Drop Ship miscellaneous fees billed: Comments:	Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday
	Priority Overnight receipt available:
Class of Trade Restriction:	PO Receipt Cut off time:
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:	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician/Clinic DEA #: Physician/Clinic Specialty:	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?