

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014					Introduction Type:	Post Launch Cha	nange		Final Version			Date:	4/11/	/2017		
			PRODUCT INFORMATI	ON					SPECIAL HANDL	ING AND STO	DRAGE REQ	JIREMENTS	*			
Company Name:	Camber Pharmaceuti	cals			Applicatio	on: ANDA	1	a. Temperature – Indic	ate the USP tempera	ature range fo	or this produ	ct.				
Application Number for ND			:	205064		l .			ature Range				en 20 and 25	C (68° – 77°		
DUNS:	82-667-4775							Other Te	emperature Range Re	aguirement						
Proprietary Name (If Applica		Name: Aripiprazo	ole Tablets 30MG 30CT						ite in)	oquiroment				1		
Selling Unit NDC:	31722-830-30	11	Individual Unit NDC:	31722-830-30	UPC: 3317	22830300		\	,					1		
UDI	NA	•	CVX Code:	•	MVX Code: NA			Is this pr	oduct to be shipped t	to customers o	on ice?		No			
Description:	Light pink to pink rour	nd tablets imprinted with 'S	99' on upper and 'I' on lower		_			Is this pr	oduct to be shipped t	to customers o	on dry ice?	•	No	-		
	5 1 1	,						'			,	•		-		
Active Ingredient(s):		Aripiprazole						b. Contact for tempera	ture excursion ques							
								Name:			Soma Raju					
URL for Additional Product I		www.camberpharma.com	n	1				Number			732-529-042					
Address: City:	1031 Centennial Avenue			State	Address 2:			Group E	-mail:		somaraju@h	eterousa.cor	n			
Key Contact:	Piscataway Customer Service				Email: customerservice@camberpharma.com			c. Special regulations	for product in any s	tatos?			No			
Phone Number:	732-529-0430			Fax:					returns requirements		ct?		No	-		
Product Therapeutic Classifi										,		•		-		
								d. Store product (unit	of sale) upright?				No			
ADDITIONA	AL PRODUCT INFORM	IATION	1		PRODUCT DESCRIPTION	INFORMATION			product (unit of sale	e) from light?		•	No	-		
Is the Product								e. Shelf life:				i	24	Months		
a legend device?		No		Size:	30				nelf life at launch (if	different):				Months		
reverse numbered?		No		Size.	30											
co-licensed?		No		Strength:	30 mg				C	ORDER INFOR	RMATION					
Is the Product		Direct-Ship Only Unit of Use			- · · · · ·			11-14-46	N-1-		\A/b-4 :- 4b-	NDC selling				
is the Product		Unit of Use		Dosage Form	n: Oral Solid tablet			Unit of S	Bottle		1 box of 48 l		unit?			
								x	Box/Carton			g. 1 Box of 10) Vials)			
If Unit Dose, is item bar code	ed to unit dose for hosp	ital scanning?		B d 4 Ob	D				Ampule		(g =				
If Unit Dose NDC, indicate N	IDC here:			Product Shap	pe: Round				Glass		Minimum o	der quantity	?	Yes		
				Product Colo	or: Light pink to pink	k			Tube							
Country of Origin		India			3 1 1				Vial Liquid Sgl							
' ' ' ' '	Is this product covered under the Trade Agreements Act (TAA)? Product Imprint: '99'/I'								A Country of the Association							
	r the Trade Agreements	s Act (TAA)?		Product Impr	int: '99'/'I'				Vial Liquid Multi		If Yes, how		cn package t	type?		
	r the Trade Agreements	s Act (TAA)? No		Product Impr	'99'/'I'				Vial Powder Sql		If Yes, how	Each		type?		
	r the Trade Agreements	s Act (TAA)? No		Product Impr	'99'/'I'									type?		
	r the Trade Agreement	s Act (TAA)? No No	FOR GENERIC DRUG PROI		'99'/'I'				Vial Powder Sql Vial Power Multi			Each Inner/Carton		type?		
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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): SDS Hazard Classification a. Cvtotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Organic Corrosive Is the product a CA Prop 65 reproductive toxicant? Inorganic Oxidizer Does the product label bear a CA Prop 65 warning? Steroid/Androgen Contact Hazard Aerosol Class; Identify NFPA Storage Level: c. Contact Hazard? No 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? REMS or REGISTRY RESTRICTIONS Is the product restricted for air shipment? If so, indicate restriction: Passenger Is there a REMS on this product? Yes Cargo If Yes, is it managed with a pharmacy registry? No N/A Passenger & Cargo Website URL: Is this a reportable quantity? No 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: No Wholesale distributor support: Small Quantity (49 CFR 173.4) No Special Permit; DOT-SP Provider Name: Site Enrollment Number assigned Special Provision (listed in Column 7 of 49 CFR 172.101); DEA #: by Supplier: No SP# PCPDP #: NPI#: No ADD'L STORAGE INFORMATION Is the Product... Comments None 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?: Contact tel. # if product received damaged: No CLASS OF TRADE RESTRICTION: Is product returnable for credit: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices No URL/Link to returns policy: contact - customerservice@camberpharma.com Restricted to retail pharmacy only: Yes 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 Proces	ssing
Purchase orders may be accepted by:		Purchase order daily receipt cut off time by supplier	
a. EDI		Cut off time:	Eastern
b. Autofax	Fax Number:		
c. Fax	Fax Number:	Shipping lead time of PO: Hours	Days
d. Phone only	Phone No.:		
e. Supplier Web Site only	Site Address:	Ships same day for next day receipt:	
Minimum Order Quantity:		Ships for second day receipt:	
Supplier's Customer Service Number:	News	Ships regular ground for 3-10 days receipt:	
Contracted 3PL company / contact #:	Name: Phone:		
From a district Charles of the Charles		Occasion to the Control of the Contr	
	arges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Pro	bcessing
Expedited freight fees billed with each ord	er:	Overnight receipt available:	
Drop Ship service fee billed with each orde	er:	PO Receipt cut off time:	Eastern
Drop Ship miscellaneous fees billed:		Days of week overnight is available:	Monday
Comments:			Tuesday
			Wednesday
			Thursday
			Friday
		Priority Overnight receipt available:	
Cl	ass of Trade Restriction:	PO Receipt Cut off time:	
No restriction: Select YES if sold to retail p	pharmacy, hospitals, clinics and physician offices	Saturday Overnight receipt available:	
Restricted to retail pharmacy only:		PO Receipt Cut off time:	
Restricted to hospital, clinics, and physicia	n offices only:	Order receipt method: Phone #:	
Restricted from US territories? (explain in	comments)	Fax: Fax #:	
Comments:		EDI:	
		Overnight Fees apply:	
		Other fees apply:	
Other Data In	formation Required to Process PO:	Return Instructions	
Patient Procedure Date:		Contact # if product is received damaged:	
Physician Name:		Is product returnable for credit:	
Physician/Clinic Phone #		URL/Link to returns policy:	
Physician State License #		Special regulations or returns requirements for this product in cer	tain states?
Physician/Clinic DEA #:		If so, which states? Other requirements? Comments?	
Physician/Clinic Specialty:			
	Miscellaneous Notes:		
		ADDITIONAL INFORMATION	
		Is product order for scheduled patient procedure?	
		Is product order for restocking purposes?	