

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014							Intro	duction Type:		New Item	00	Final Version			Date:			
				PRODUCT INFORMA	TION							SPECIAL HANDLI	ING AND ST	ORAGE REQ	JIREMENTS	*		
Company Name:	Camber Pharmaceuticals Application: NDA/ANDA/BLA (drug); PMA/510(k)(med device): 212133						on:	ANDA	a. Temperature – Indicate the USP temperature range for this product. Temperature Range Controlled Room – between 20 and 25 C (68° – 77°									
DUNS:	826774775					1					-	emperature Range Re	auiromont				- (
Proprietary Name (If Applical		Name:	HYDROMO	ORPHONE HYDROCHLOR	RIDE EXTEN	DED RELEASE	TABLETS	12MG 100CT				vrite in)	quirement				1	
Selling Unit NDC:	31722-120-01			Individual Unit NDC:				UPC:			11	,					ı	
UDI				CVX Code:			MVX	Code:			Is this	product to be shipped to	o customers	on ice?		No		
Description: Light yellow to yellow film coated, round, biconvex tablets printed with '267' in black ink on one side of the tablet.								Is this product to be shipped to customers on dry ice? No										
Active Ingredient(s): Hydromorphone Hydrochloride									b. Contact for temperature excursion questions: Name: Soma Raju									
URL for Additional Product In	al Product Information: www.camberpharma.com								Numbe	732-529-0423								
Address:	1031 Centennial Avenue					Address 2:					E-mail:		somaraju@h	neterousa.cor	m			
City:	Piscataway State: NJ Zip: 08854																	
Key Contact:	Customer Service					Email: customerservice@camberpharma.com Fax: 732-562-8788					s for product in any s				No No	•		
Phone Number:	732-529-0430					732-562-8788				Special returns requirements for this product? No								
Product Therapeutic Classification:										d. Store product (unit of sale) upright? No								
ADDITIONAL PRODUCT INFORMATION PRODUCT DESCRIPTION INFORMATION										Protect product (unit of sale) upright? Protect product (unit of sale) from light? Yes						•		
Is the Product											e. Shelf life:				:	24	Months	
a legend device?			No								Initial shelf life at launch (if different):				ļ	24	Months	
reverse numbered?	I				Size: 100						•							
co-licensed?	-licensed? No Stree					Strength:	Strength: 12MG				ORDER INFORMATION							
Is the Product		Direct-Ship On	ly								ll			140	NDO III	140		
Is the Product		Neither				Dosage Form	: 1	Tablet			Unit of	Bottle		1 bottle of 1	NDC selling	unit?		
							L					Box/Carton			g. 1 Box of 1	0 Vials)		
If Unit Dose, is item bar code	ed to unit dose for hospi	ital scanning?	No			Product Shap	[Round				Ampule		,		,		
If Unit Dose NDC, indicate NI	DC here:					Froduct Snap	e.	Round				Glass		Minimum o	rder quantity	/?	Yes	
		luo				Product Color	r: L	Light yellow to y	ellow			Tube						
Country of Origin		USA					-				Vial Liquid Sgl Vial Liquid Multi If Yes, how many of which package type?							
Is this product covered under	r the Trade Agreements	Act (TAA)?				Product Impri	int: 2	267			Vial Powder Sql 24 Each							
		•	_				<u>L</u>					Vial Power Multi			Inner/Carton	ı/Pack		
												Other: Write In	_		Case			
			F	FOR GENERIC DRUG PR	RODUCTS													
					i	X Autho	orized Gene	aric *If Δ	uthorized C	Seneric, other section		PHAR	MACY ORD	ER / BILL UNI	Т			
I. Orange Book Rating:	AB					X Additi	onzed Gene		s are not a									
II. Generic Equivalent to Wha		Hydromorphon	e HCL ER T	Tablets							Rec. sell unit to customer? Rx billing unit to pharmacy:							
In Solicito Esparation to Trial District.									(Write-in, e.g. 1 Vial)									
		DRU	G SUPPLY (CHAIN SECURITY ACT ((DSCSA) INF	ORMATION									Milliliter			
		_		.,			00.17000											
Does supplier meet DSCSA or Is product exempt from DSCS		urer?	No	Yes	GLI	N:	03172200	00000			ITEM AND PACKING INFORMATION							
If yes, select exemption:	JA!		140										Dime	ensions (US m	ısmts.)	Volume		
Other exemption - Write in:												Weight Lbs.	Depth	Height	Width	(Cube)	# Pieces:	
Is product repackaged?			No				al product	purchased dire	ect		Item:	0.098		3.225	1.835			
Is product sold by manufactu				No		m mfr?						0.000		0.220	1.000			
Has FDA granted waiver/exce	eption/exemption for p	product?		No	If y	es, attach doci	umentation	n from FDA.			Box/Carton/Bundle/ Inner Pack:				1			
				GTIN PRODUCT INFOR	MATION						Case:							
					Saleable						III ousc.	2.3	12.3	3.8	8.3	0.224	24	
				Level	Unit			Quai	ntity G	TIN-14	Pallet:							
Serialized?	Yes	_	x Ite			X 2D		Linear 1	00	0331722120012								
If not, when?				ox/Carton/Bundle/Inner Pack		2D		Linear	_ _	2001700100010	UPC:	Case:						
Items aggregated?	No	-		ase	х	X 2D		Linear 24	1 10	0331722120019		Carton:						
	Pallet 2D Linear 2D Linear									COST INFORMATION WHOLESALER USE ONLY:								
						2D		Linear										
						2D		Linear			Regular Cost			Vendor #:	ļ			
	20 Linear Linear							Invoice Cost (WAC) (Whsl. Code #:								
											Federal Excise Tax P	er Unit of Sale		Fineline Co	de:			
											As of date:			+				
			Δ#-	ach conv of SAFETY DA	TA SHEET /SI	DS) or non haz-	ard letter D	ACKAGE INSE	RT I ARFI	AND PHOTO OF PRO	DDUCT PACKAGING and	BARCODE		1				
*Please provide any addition	al information on pag	e 2.	Alle	ao sopy of ortical DAI	511221 (01	o, or non nazi		p. 3 for Design			Signat							



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? 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? d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) Is the product a NIOSH hazardous drug? e. Does the product contain DEHP? If yes, indicate which: Is this product regulated for shipment by DOT or IATA? (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? 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? 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: Wholesale distributor support: Small Quantity (49 CFR 173.4) Special Permit; DOT-SP Provider Name: Site Enrollment Number assigned Special Provision (listed in Column 7 of 49 CFR 172.101); DEA #: by Supplier: SP# PCPDP #: NPI#: ADD'L STORAGE INFORMATION Is the Product... Comments Controlled Substance? Controlled by State(s)? Registry: ARCOS Reportable? Registry Program Contact Name: Schedule No. (inc. N for non-narcotic) Comments Controlled Substance Code Listed Chemical (List I or II) RETURN INSTRUCTIONS If yes, indicate which: Is it a scheduled listed chemical product?: Contact tel. # if product received damaged: 732-529-0430 CLASS OF TRADE RESTRICTION: Is product returnable for credit: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices URL/Link to returns policy: contact - customerservice@camberpharma.com No Restricted to retail pharmacy only: Special regulations or returns requirements for this product in certain states? Restricted to hospital, clinics, and physician offices only: If so, which states? Other requirements? Comments? Restricted from US territories? (explain in comments) 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:	Purchase order daily receipt cut off time by supplier							
a. EDI	Cut off time: Eastern							
b. Autofax Fax Number:	1							
c. 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:	Ships regular ground for 3-10 days receipt:							
Contracted 3PL company / contact #: Name:								
Phone:								
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:							
Drop Ship miscellaneous fees billed:	Days of week overnight is available: Monday							
Comments:	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 No	Saturday Overnight receipt available:							
Restricted to retail pharmacy only: No	PO Receipt Cut off time:							
Restricted to hospital, clinics, and physician offices only: No	Phone #							
Restricted from US territories? (explain in comments)	Order receipt method: Fax: Fax #:							
Comments:	EDI:							
	Overnight Fees apply:							
	Other fees apply:							
Other Data Information 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 certain 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?							
	<u> </u>							