

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014						Introduction Type:	New Item	00	Final Version			Date:		
			PRODUCT INFORMA	ATION					SPECIAL HANDL	ING AND STO	DRAGE REQ	JIREMENTS	*	
Company Name:	Camber Pharmaceution	cals				Application	n: ANDA	a. Temperature – In	dicate the USP temper	rature range f	or this produ	ct.		
	or NDA/ANDA/BLA (drug); PMA/510(k)(med device):			212133	212133			Temperature Range Controlled Room – between 20 and 25 C (6					C (68° – 77°	
DUNS:	826774775							Other	Temperature Range Re	equirement				
Proprietary Name (If Applicate		Name: HYDRON	MORPHONE HYDROCHLO	ORIDE EXTENDED	RELEASE TABL	ETS 32MG 100CT			(write in)	equilement				1
	31722-122-01		Individual Unit NDC:			UPC:			(
UDI		•	CVX Code:			MVX Code:		Is this	product to be shipped	to customers of	on ice?		No	
Description:							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					Address 2:			Number: Group E-mail:			732-529-0423 somaraju@heterousa.com			
Address: City:	1031 Centennial Avenue Address 2:					08854	Grou	p E-mail:		somaraju@r	ieterousa.cor	n		
	Customer Service					tomerservice@cambe		c Special regulation	ns for product in any s	states?			No	
Phone Number:	732-529-0430					-562-8788	i pridi mai som	c. Special regulations for product in any states? Special returns requirements for this product? No						-
Product Therapeutic Classific	ication:] '		•		•		
•								d. Store product (ur	nit of sale) upright?				No	
ADDITIONAL	AL PRODUCT INFORM	ATION			PRODI	UCT DESCRIPTION II	NFORMATION		ct product (unit of sale	e) from light?		•	Yes	-
Is the Product								e. Shelf life:					24	Months
a legend device?		No		Siz		100		Initia	shelf life at launch (if	different):				Months
reverse numbered?		No		312	e.	100								•
co-licensed?		No		Str	ength:	32MG			(ORDER INFOR	RMATION			
Is the Product		Direct-Ship Only Neither			_			ll limit	of Sale		M/hat is the	NDC selling	unit?	
is the Product		Neither		Dos	sage Form:	Tablet		X			I bottle of 10		unitr	
									Box/Carton			g. 1 Box of 10	0 Vials)	
If Unit Dose, is item bar coded	ed to unit dose for hospi	ital scanning?		Bro	oduct Shape:	Round			Ampule		,	•	,	
If Unit Dose NDC, indicate ND	DC here:			FIC	ouuci Shape.	Round			Glass		Minimum o	der quantity	?	Yes
				Pro	oduct Color:	White to off-white	1		Tube					
									Vial Liquid Sql					
Country of Origin		USA						II —			16 Van ha		ab maakama 4	
Country of Origin Is this product covered under		Act (TAA)?		Pro	oduct Imprint:	269			Vial Liquid Multi				ch package t	type?
, ,				Pro	oduct Imprint:	269			Vial Liquid Multi Vial Powder Sql			Each		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? 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:	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?
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