

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014							Introd	duction Type:		Post Launch Change		Final Version			Date:	4/17	7/2017
				PRODUCT INFO	RMATION							SPECIAL HANDL	LING AND ST	ORAGE REQ	UIREMENTS	*	
Company Name: Application Number for ND	Camber Pharmaceut		d device):		2	02801		Application	n: [ANDA	a. Temperature – India Tempera	cate the USP temper ature Range	rature range			en 20 and 25	5 C (68° – 77° ł
DUNS:	82-667-4775		u uorioo).		L						-	emperature Range Re	quiromont				
Proprietary Name (If Applical		Name:	Levofloxac	in Tablets 250MG 50	OCT							rite in)	quirement				٦
Selling Unit NDC:	31722-721-50			Individual Unit N		31722-721-50		UPC: 33172	2272150	09							
UDI	NA			CVX Code:			MVX	Code: NA			Is this pr	oduct to be shipped t	to customers	on ice?		No	_
Description:	Pink, capsule shaped	d tablets embosse	ed with '25'	on upper punch and	'T' on lower						Is this pr	oduct to be shipped t	to customers	on dry ice?		No	_
Active Ingredient(s): Levofloxacin								b. Contact for temperature excursion questions: Name: Soma Raju									
URL for Additional Product I	Information:	www.camberph	narma.com								Number	:		732-529-04	23		
Address:	1031 Centennial Ave	nue					Address				Group E	somaraju@heterousa.com					
City:					State:												
Key Contact:	Customer Service				Email: customerservice@camberpharma.com Fax: 732-562-8788				c. Special regulations	for product in any s returns requirements		a+2		No No	_		
Phone Number: Product Therapeutic Classifi	732-529-0430			Fax: //32-562-8/88			Special	returns requirements	ioi uns produ	IGT ?		INU	-				
Froduct merapeutic classif	ication.										d Store product (unit	of sale) upright?				No	
ADDITION	AL PRODUCT INFORM	NATION					PRODUCT I	DESCRIPTION I	INFORM	ATION	d. Store product (unit of sale) upright? No Protect product (unit of sale) from light? No						
Is the Product											e. Shelf life:		.,			24	Months
a legend device?			No			0	-	0				nelf life at launch (if o	different):				Months
reverse numbered?			No			Size:	5	0				-					_
co-licensed?			No			Strength:	2	50 mg				(order info	RMATION			
Is the Product		Direct-Ship On	ly			J. J. J.	_	5			11.2.1			M/h =4 is 4h s			
Is the Product		Unit of Use				Dosage Form	: C	Dral solid tablet			Unit of S	Bottle		1 box of 12	NDC selling	unit?	
							_				x	Box/Carton			.g. 1 Box of 1	0 Vials)	
If Unit Dose, is item bar code	ed to unit dose for hosp	oital scanning?				Product Shap		apsule shape				Ampule		(, .	5	,	
If Unit Dose NDC, indicate N	IDC here:					Froduct Shap	<i>.</i> .	apsule shape				Glass		Minimum o	rder quantity	/?	Yes
		India				Product Color	r: p	ink				Tube					
Country of Origin							-					Vial Liquid Sgl Vial Liquid Multi		If Yes how	many of whi	ich package	type?
Is this product covered under	r the Trade Agreement	s Act (TAA)?	No			Product Impri	int: 2	5'/'T'				Vial Powder Sql		1 103,1101	Each	en puekage	type:
		-										Vial Power Multi		12	Inner/Cartor	v/Pack	
												Other: Write In			Case		
				FOR GENERIC DRU	G PRODUCTS						_						
Authorized Generic *If Authorized Generic, other section										PHAF	RMACY ORD	ER / BILL UNI	Т				
I. Orange Book Rating:	AB									applicable	Rec. sell unit to customer? Rx billing unit to pharmacy:						
II. Generic Equivalent to What		Levaquin									Each						
											(Write-in, e.g. 1 Vial)				Gram		
		DRU	JG SUPPLY	CHAIN SECURITY	ACT (DSCSA) 🛚	FORMATION									Milliliter		
D				Vee										G INFORMATI			
Does supplier meet DSCSA Is product exempt from DSC		aurer?	No	Yes		BLN:						TEMA		S-INFORMATI			
If yes, select exemption:				-								M	Dime	ensions (US m	nsmts.)	Volume	" D '
Other exemption - Write in:	:											Weight Lbs.	Depth	Height	Width	(Cube)	# Pieces:
Is product repackaged?			No			Yes, was origina	al product p	ourchased dire	ct		ltem:	0.15		3.625	1.5		
Is product sold by manufact Has FDA granted waiver/exc				No No		rom mfr? ves, attach doc	umontot:	from EDA			Box/Carton/Bundle/		-				
nas PDA granted walver/exc	eption/exemption to	product?		INU	n	yes, attach doc	umentation	nom FDA.			Inner Pack:	1.75	6.75	3.875	5	0.076	12
				GTIN PRODUCT IN	IFORMATIO <u>N</u>						Case:	17.5	14.5	8.875	44.5	0.856	96
					Saleable							17.5	14.5	8.875	11.5	0.856	96
				Level	Unit			Quant		GTIN-14	Pallet:						4800
Serialized?	Yes	-	A	em		x 2D		inear 1		00331722721509		0					
If not, when? Items aggregated?	Yes	┛		Box/Carton/Bundle/Inner Case	Pack x	x 2D x 2D		inear 12 inear 96		10331722721506 30331722721500	UPC:	Case: Carton:					
items aggregated?	165			Pallet		2D 2D		inear		30331722721300		Carton.					
						2D		inear			COST	INFORMATION			WHOLESAI	LER USE ON	LY:
		[2D	L	inear								_	
						2D		inear	_ [Regular Cost			Vendor #:			
2D Linear						Invoice Cost (WAC) (\$) \$16.82 Federal Excise Tax Per Unit of Sale				WhsI. Code #: Fineline Code:							
											As of date:	er Unit Of Sale		rineline Co	ae:		
	Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.																
*Please provide any additional information on page 2. See new p. 3 for Designated Trop Ship Only. Signature:																	
*Please provide any addition	nal information on da	r wasc promo any auditional minimation on page 4.															



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

le this preduct (sheet all that apply).								
Is this product (check all that apply): a. Cytotoxic? No	SDS Hazard Classification							
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?								
Is the product a CA Prop 65 carcinogen? No	Organic Corrosive							
Is the product a CA Prop 65 reproductive toxicant?	Inorganic Oxidizer							
Does the product a CA Prop 65 reproductive toxicant?								
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard							
c. Contact Hazard? No								
	Aerosol Class; Identify NFPA Storage Level:							
(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								
b. Proper Shipping Name	Hazardous Waste Identification							
c. DOT Hazard Class	EPA Hazardous Waste Code: NA							
d. Packing Group								
e. Inhalation Hazard?								
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS							
Passenger	Is there a REMS on this product? No							
Cargo	If Yes, is it managed with a pharmacy registry? No							
Passenger & Cargo	Website URL: N/A							
Is this a reportable quantity? No								
RQ Threshold:	Comments / Details: (For example, iPledge program?)							
Is this a marine pollutant? No	None							
Is this product shipped utilizing an authorized DOT exception or Special Permit?								
No (if yes, identify method below)	REMS: No							
Limited Quantity	REMS Program Manager Name: Phone:							
Consumer Commodity, ORM-D	Supplier Manages REMS registry exclusively: No							
Small Quantity (49 CFR 173.4)	Wholesale distributor support: No							
Special Permit; DOT-SP	Provider Name:							
Special Provision (listed in Column 7 of 49 CFR 172.101);	Site Enrollment Number assigned DEA #: No							
SP#	by Supplier: PCPDP #: No							
	NPI #: No							
ADD'L STORAGE INFORMATION								
Is the Product	Comments None							
Controlled Substance? No								
Controlled by State(s)? No	Registry: No							
ARCOS Reportable? No	Registry Program Contact Name: Phone:							
Schedule No. (inc. N for non-narcotic)	Comments							
Controlled Substance Code								
Listed Chemical (List I or II) No	RETURN INSTRUCTIONS							
If yes, indicate which:								
Is it a scheduled listed chemical product?: No	Contact tel. # if product received damaged: 732-529-0430							
CLASS OF TRADE RESTRICTION:	Is product returnable for credit: Yes							
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	Special regulations or returns requirements for this product in certain states? No							
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:								
	NEOUS NOTES and/or Image of Product Barcode:							
MISCELLA								



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: Autofax Yes b. Autofax No Fax Number: c. Fax Yes Fax Number: d. Phone only No Phone No.: e. Supplier Web Site only No Site Address: Minimum Order Quantity: case pack 732-529-0430 x466 x465 x467 x470 Contracted 3PL company / contact #: Name: Phone:	Purchase order daily receipt cut off time by supplier Cut off time: 2:30PM Eastern Shipping lead time of PO: 24/48 Hours Days Ships same day for next day receipt: No No Ships for second day receipt: No No Ships regular ground for 3-10 days receipt: Yes						
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing						
Expedited freight fees billed with each order: No Drop Ship service fee billed with each order: No Drop Ship miscellaneous fees billed: No Comments: Image: No Comments: Image: No Class of Trade Restriction: No Restricted to retail pharmacy, hospitals, clinics and physician offices No Yes Restricted to nospital, clinics, and physician offices only: No Restricted from US territories? (explain in comments) No	Overnight receipt available: Yes PO Receipt cut off time: 2:30PM Eastern Days of week overnight is available: X Monday X Tuesday Wednesday X Thursday Friday Priority Overnight receipt available: Yes PO Receipt Cut off time: 2:30PM EST Saturday Overnight receipt available: No PO Receipt Cut off time: No Order receipt method: Phone: No Fax: Yes Fax #:						
Comments:	rax. res rax #. res EDI: Yes Overnight Fees apply: Yes Other fees apply: No						
Other Data Information Required to Process PO:	Return Instructions						
Patient Procedure Date:	Contact # if product is received damaged: 732-529-0430 Is product returnable for credit: Yes URL/Link to returns policy:						
	ADDITIONAL INFORMATION						