

## **Standard Pharmaceutical Product Information (Rx Product Only)**

© August 2014 Post Launch Change Final Version Date: 4/17/2017															
			PRODUCT INFORMAT	ION						SPECIAL HANDL	ING AND ST	ORAGE REQ	UIREMENTS	*	
Company Name:	Camber Pharmaceuti	rals				Application	on:	ANDA	a. Temperature – Indi	rate the LISP temper	raturo rango	for this prod	uct		
Application Number for ND			:	202801						ature Range	idiale lange			en 20 and 25	C (68° – 77° F
DUNS:	82-667-4775		·						-	=					
Proprietary Name (If Applicat		Name: Loveflove	acin Tablets 500MG 50CT							emperature Range Re rite in)	equirement				1
Selling Unit NDC:	31722-722-50	Name. Levonoxa	Individual Unit NDC:	31722-722	-50	UPC: 331	72272250	6	-   (w	iile iii)					J
UDI	01722 722 00		CVX Code:	01722 722		/X Code:	12212200	<u> </u>	Is this n	roduct to be shipped to	n customers o	on ice?		No	
	0	and the later and a second and the							<b>=</b> 1						-
Description:	Orange, capsule snap	ded labiets embossed with	'26' on upper punch and 'T'	on lower					is this p	roduct to be shipped to	o customers t	on ary ice?		No	_
Active Ingredient(s):		Levofloxacin							b. Contact for temper	ature excursion que	estions.				
						Name:	ataro oxoaroion quo		Soma Raju						
URL for Additional Product Information: www.camberpharma.com								Number	:		732-529-0423				
Address:	1031 Centennial Avenue Address 2:					Group E-mail: somaraju@heterousa.com				m					
City:	Piscataway			State		Zip:		8854							
Key Contact:	Customer Service			Email		nerservice@camb	erpharma.	.com	c. Special regulations					No	_
Phone Number:	732-529-0430	0430 Fax: 732-562-8788					Special returns requirements for this product?  No								
Product Therapeutic Classifi	ication:														
									d. Store product (unit					No	_
ADDITIONA	AL PRODUCT INFORM	ATION			PRODUC	CT DESCRIPTION	I INFORM <i>A</i>	ATION	Protect	product (unit of sale	e) from light?	1		No	=
Is the Product									e. Shelf life:					24	Months
a legend device?		No		Size:		50			Initial st	nelf life at launch (if o	different):				Months
reverse numbered?		No									ORDER INFO	DMATION			
co-licensed?		No Direct-Ship Only		Strength:		500 mg				(	ORDER INFO	RMATION			
Is the Product Is the Product		Unit of Use							Unit of S	Sale		What is the	NDC selling	unit?	
is the Froduct		Gill of Coo		Dosage Fo	orm:	Oral solid tablet			Only or v	Bottle		1 box of 12		u	
W 11-7 B		9-1				L			x	Box/Carton			.g. 1 Box of 1	0 Vials)	
If Unit Dose, is item bar code	ed to unit dose for nosp	ital scanning?		Product S	hano:	capsule shape				Ampule					
If Unit Dose NDC, indicate NI	DC here:			Floudet S	iiape.	capsule shape				Glass		Minimum o	rder quantity	/?	
				Product C	olor:	orange				Tube					
Country of Origin		India				_			Vial Liquid Sgl Vial Liquid Multi If Yes, how many of which package type?						
Is this product covered under the Trade Agreements Act (TAA)? No Product Imprint: 26/T						Vial Powder Sql		ir res, now	Each	сп раскаде	type?				
		140							'II <del></del>	Vial Power Multi		12	Inner/Cartor	/Pack	
L				L					-1	Other: Write In			Case		
			FOR GENERIC DRUG PRO	DDUCTS									_		
					uthorized Ge			Generic, other section		PHAF	RMACY ORDE	R / BILL UN	Ţ		
I. Orange Book Rating:	AB					TIEIO	ls are not a	арріісавіе	Rec. sell unit to customer? Rx billing unit to pharmacy:						
II. Generic Equivalent to What Brand?: Levaquin					Each										
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION						(Write-in, e.g. 1 Vial)				Gram Milliliter					
		DRUG SUFFI	T CHAIN SECONTT ACT (I	DOCOA) IN ORMATION									williller		
Does supplier meet DSCSA	definition of manufac	turer?	Yes	GLN:						ITEM A	ND PACKING	INFORMATI	ON	_	
Is product exempt from DSC			No												
If yes, select exemption:										Weight Lbs.	Dime	nsions (US m	nsmts.)	Volume	# Pieces:
Other exemption - Write in:	:									Weight Ebs.	Depth	Height	Width	(Cube)	#110003.
Is product repackaged?			No		ginal produc	ct purchased dir	ect		Item:	0.1		3	1.375		
Is product sold by manufact			No No	from mfr? If yes, attach		: f FDA			Box/Carton/Bundle/		_				
Has FDA granted waiver/exc	eption/exemption for	product?	INO	ir yes, attach o	ocumentat	ion from FDA.			Inner Pack:	1.2	6.625	3	4.875	0.056	12
			GTIN PRODUCT INFORM	ATION					Case:						
				Saleable					111	12.45	14.5	8	11.5	0.772	96
			Level	Unit		Qua	intity G	GTIN-14	Pallet:						4800
Serialized?	Yes	х	Item	<b>x</b> 20		Linear 1		00331722722506							4600
If not, when?		x	Box/Carton/Bundle/Inner Pack	x x 20		Linear 1:		0331722722503	UPC:	Case:					
Items aggregated?	Yes	х	Case	X 20		Linear 9	6 3	80331722722507		Carton:					
			Pallet	20		Linear	<b></b>    -		2007	INFORMATION			WHOLESH	ER USE ON	I V.
				20		Linear			COST	INFORMATION			WHOLESAL	LER USE ON	-11
		$\vdash$		20		Linear			Regular Cost			Vendor #:			
		$\vdash$		20		Linear			Invoice Cost (WAC) (\$	5)	\$19.28	-	#:		
									Federal Excise Tax Pe		J.U.20	Fineline Co			
									As of date:						
			Attach copy of SAFETY DA	TA SHEET (SDS) or nor	hazard lette	r, PACKAGE INSI	ERT, LABE	EL AND PHOTO OF PR	ODUCT PACKAGING and Ba	ARCODE.					
*Please provide any addition	nal information on pag	je 2.			See ne	ew p. 3 for Desig	nated Dro	p Ship Only.	Signatu	re:					



## **Standard Pharmaceutical Product Information (Page 2)**

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL F	HAZARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply):							
a. Cytotoxic?	SDS Hazard Classification						
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	ODO Hazara Glassification						
Is the product a CA Prop 65 carcinogen?	Organic Corrosive						
Is the product a CA Prop 65 carcinogen?	Inorganic Oxidizer						
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard						
- O-start HannelO	A arrest Olean Identify NEDA Otenana Laval						
c. Contact Hazard?	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?							
(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							
Cargo							
Passenger & Cargo	Website URL:						
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	<u> </u>					
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		<u></u>					
Is the Product	Comments None						
Controlled Substance?							
Controlled by State(s)?	Registry: No						
ARCOS Reportable?	Registry Program Contact Name:	Phone:					
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:							
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@ca	amberpharma.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:							
MICCELLAN	IEOUS NOTES and/or Image of Product Barcode:						
MISCELLAR	VEOUS NOTES and/or image of Froduct 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  b. Autofax  Yes  No Fax Number:	Purchase order daily receipt cut off time by supplier Cut off time: 2:30PM Eastern					
c. Fax  d. Phone only  No Phone No.:	Shipping lead time of PO: 24/48 Hours Days					
e. Supplier Web Site only No Site Address:	Ships same day for next day receipt: No					
Minimum Order Quantity: case pack	Ships for second day receipt:  No					
Supplier's Customer Service Number: 732-529-0430 x466 x465 x467 x470	Ships regular ground for 3-10 days receipt:  Yes					
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: No No	Overnight receipt available: Yes					
Drop Ship service fee billed with each order: No No	PO Receipt cut off time: 2:30PM Eastern					
Drop Ship miscellaneous fees billed: No	Days of week overnight is available:					
Comments:	x Tuesday x Wednesday Thursday x Friday					
	Priority Overnight receipt available: Yes					
Class of Trade Restriction:	PO Receipt Cut off time: 2:30PM EST					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices No	Saturday Overnight receipt available: No					
Restricted to retail pharmacy only:  Yes	PO Receipt Cut off time:					
Restricted to hospital, clinics, and physician offices only:  No	Order receipt method:  No Phone #:					
Restricted from US territories? (explain in comments)  No	Fax: Yes Fax #: 732-562-8788					
Comments:	EDI: Yes					
	Overnight Fees apply:  Other fees apply:  No					
Other Data Information Demoired to Decree DO						
Other Data Information Required to Process PO:	Return Instructions					
Patient Procedure Date:  Physician Name:	Contact # if product is received damaged:  Is product returnable for credit:  Yes					
Physician/Clinic Phone #	URL/Link to returns policy:					
Physician State License #	Special regulations or returns requirements for this product in certain states?  Yes					
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?					