

Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2021						Introduction 1	Гуре:	New Item		Final Version			Date:	7/2/2	2024
			PRODUCT INFORMAT	TION						SPECIAL HAN	DLING AND STOR	RAGE REQUI	REMENTS*		
Company Name:	SOLA Pharmaceuticals					Applica	tion:	ANDA	a. Temperature -	Indicate the USP temper	erature range for t	his product.			
Application Number for NDA/AN		(med devic	e):	A2*	17904					mperature Range	Controlled Room		and 25 C (68	3° – 77° F)	
Medical Device Class, if applica	ble:														
DUNS:	080121345								Oth	er Temperature Range I	Requirement				
Proprietary Name (If Applicable) a		Ofloxad	cin Ophthalmic Solution 0.3%	6						(write in)					
Selling Unit NDC:	70512-793-10		Unit of Use NDC:			UPC:	37051279	93104	No	tes					
UDI			CVX Code:			MVX Code:									
Description:	Ofloxacin Ophthalmic Solut	ion USP, 0.3	3%, 10mL							his product to be shipped				No	
A office to one discording	06								ls t	his product to be shipped	d to customers on o	dry ice?		No	
Active Ingredient(s):	Ofloxac	n							h Contact for ten	perature excursion qu	ostions.				
URL for Additional Product Inform	nation:									me:	estions.				
Address:	655 Highlandia Dr.					Address 2:				mber:		866-747-736	35		
City:	Baton Rouge				State:	LA	Zip: 7	70810	Gre	oup E-mail:		info@sola	meds.us		
Key Contact:					Email:	info@solamed	ls.us								
Phone Number:	866-747-7365				Fax:	800-754-9550				ions for product in any				No	_
Product Therapeutic Classification	Fluoroq	inolone ant	ibiotics						Spi	ecial returns requirement	s for this product?			No	
	ADDITIONAL PR	ODLICT INE	TORMATION .			PRODUCT	DESCRIPT	ION INFORMATION		!4 - 6 1-1				V	1
The second section	ADDITIONAL PR	ODOCI INF		Diseast Chin C	mals s	PRODUCTI	DESCRIP!	TON INFORMATION		unit of sale) upright?				Yes	1
The product is? a legend device?	No		Is the Product	Direct-Ship O Unit of Use	riiy		40	lmL	e. Shelf life:	otect product (unit of sa	ile) from light?			Yes 24	Months
if yes, enter class #	INO		Orphan Drug Status	July Ol O26		Size:	10	IIIL		ial shelf life at launch (if different):			24	Months
a product kit?	No		orpilan Drug GlataG				0.3	3%							1
if yes, list NDCs of			FDA Approval Status			Strength:					ORDER INFORM	MATION			
component parts						Dosage Forr	m· Sc	olution; Ophthalmic							
reverse numbered?	No					Doougo : o				it of Sale			NDC selling	unit?	
co-licensed?	No		Allergens Present							x Bottle		1 Bottle	4 D64	0) (- 1 -)	
preservative-free?	Yes Yes	_				Product Sha	ipe:			Box/Carton Ampule		(vvrite-in, e	.g. 1 Box of 1	u viais)	
correctional institution block?	No									Glass		Minimum o	rder quantity	12	Yes
opioid?	No					Product Cole	or:			Tube		······································	ruor quaritity	· ·	103
Cannabinoid?	No		Country of Origin	India		Product Imp	rint.			Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for					Productilip	WIIIL.			Vial Liquid Multi				ich package t	type?
hospital scanning?			Is this product covered un							Vial Powder Sql		48	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (T	AA)?	No					Vial Power Multi Other: Write In			Inner/Cartor	n/Pack	
			FOR GENERIC DRUG PRO	DUCTS					_	Other: write in			Case		
			FOR GENERIC DRUG FRO	DUCIS											
					Au	uthorized Generic	*If Author	ized Generic, other		PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AT						section fi	elds are not applicable	Rec. sell unit to c	ustomer?		Rx billing u	nit to pharm	acy:	
II. Generic Equivalent to What Bra	and?: Ocuflox								1	Bottle	1	х	Each		
									(Write-in, e.g. 1 V	al)	-		Gram		
	DF	UG SUPPL	Y CHAIN SECURITY ACT (I	DSCSA) INFOR	MATION								Milliliter		
Does supplier meet DSCSA defin	ition of manufacturor?		Yes		GLN:	0370512000004				ITEN	I AND PACKING I	NEORMATIO	N		
Is product exempt from DSCSA?	ition of manufacturer.		No		OLIV.	0070012000004					.,				
If yes, select exemption:					GCP:	0370512			i		Dimensi	ions (US msn	nts.)	Volume	Saleable #
Other exemption - Write in:					001.	0070012			-	Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No			riginal product pur	chased		Item/Each:	0.0613	1.4567	1.378	2.7953	5.6110968	1
Is product sold by manufacturer's			No		direct from n						1.4507	1.370	2.1900	3.0110300	'
Has FDA granted waiver/exception			No		Provide sour	rce manufacturer fo	or repacka	ged product	Box/Carton/Bund Inner Pack:	le/				0	
If yes, attach documentation fro	m FDA.								Case:						
		GTIN	N AND HIBCC PRODUCT IN	IFORMATION					Case.	3.3819	9.0551	5.7087	6.1024	315.45044	48
									Pallet:	638.742	48	40	47.44	91084.8	8,640
Saleable Unit of Measure	Saleable C	uantity	HIBCC			IN-14	L	Jnit of Use GTIN-14		030.742	40	40	47.44	91004.0	0,040
X Item/Each	1				003	370512793104				OCCUPATION A TION			MILOL FOR	ED LIGE ON	V
Box/Carton/Bundle/Inner Pack	48				503	370512793109				COST INFORMATION			WHOLESAL	ER USE ONL	16
X Case Pallet	48				503	010012190109			Regular Cost			Vendor #:			
									Invoice Cost (WA	C) (\$)	\$12.00	Whsl. Code	#:		
										, , , ,	7:2:00	Fineline Co			
									As of date:	3/7/2025					
									11			1			
									11						
 			Attach copy of SAFETY DA	TA OLIFET (22	0)		- INCEDT	ADEL AND DUOTS SE	DDODUOT DAOUT SI	IO I DADOODE					



Comments:

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Version 2021 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 No a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? No x Organic Corrosive Is the product a CA Prop 65 reproductive toxicant? Inorganic Oxidizer No Does the product label bear a CA Prop 65 warning? Steroid/Androgen No Contact Hazard c. Contact Hazard? Does the product have an Aerosol class? If yes, No No identify NFPA Storage Level: d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) NFPA Storage Level: e. Does the product contain DEHP? No Is this product regulated for shipment by DOT? No Is the product a NIOSH hazardous drug? No (if yes, answer a-e below and provide SDS) If yes, indicate which: a. UN/Identification Number b. Proper Shipping Name Hazardous Waste Identification c. DOT Hazard Class d. Packing Group EPA Hazardous Waste Code: Waste Characteristics e. Inhalation Hazard? No Is this product regulated for shipment by IATA? No (if yes, answer a-e below and provide SDS) **REMS or REGISTRY RESTRICTIONS** a. UN/Identification Number b. Proper Shipping Name Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? c. DOT Hazard Class No d. Packing Group Website URL: e. Inhalation Hazard? No Is the product restricted for air shipment? If so, indicate restriction: Med Guide Required No No Passenger Limited Distribution Requirement No Comments / Details: (For example, iPledge program?) Cargo Passenger & Cargo Is this a reportable quantity? REMS: No Phone: RQ Threshold: REMS Program Manager Name: Is this a marine pollutant? Supplier Manages REMS registry exclusively: Wholesale distributor support: Is this product shipped utilizing an authorized DOT exception or Special Permit? Provider Name: (if yes, identify method below) DEA #: Limited Quantity Site Enrollment Number assigned NCPDP# Consumer Commodity, ORM-D by Supplier: NPI#: Small Quantity (49 CFR 173.4) Special Permit: DOT-SP Comments Special Provision (listed in Column 7 of 49 CFR 172.101); SP# Registry: Phone: Registry Program Contact Name: ADD'L STORAGE INFORMATION Comments Is the Product RETURN INSTRUCTIONS Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) No 866-747-7365 ARCOS Reportable? No If yes, indicate which: Contact tel. # if product received damaged: Schedule No. Is it a scheduled listed chemical product?: Yes Is product returnable for credit: CLASS OF TRADE RESTRICTION: URL/Link to returns policy: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes Restricted to retail pharmacy only: No Special regulations or returns requirements for this product in certain states? Restricted to hospital, clinics, and physician offices only: No No Restricted from US territories? (explain in comments) If so, which states? Other requirements? Comments? No

MISCELLANEOUS NOTES and/or Image of Product Barcode



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FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Purchase orders may be accepted by: a. EDI b. Autofax c. Fax d. Phone only e. Supplier Web Site only Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone: Expedited Freight Charges or Other Designated Drop Ship Fees: Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Cut off time: Ships are daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Shipping lead time of PO: Shipping lead time of PO: Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt: Ships receipt was a second and priority overnight polycomes. Devenight receipt was a second and priority overnight polycomes. Devenight receipt was a second and priority overnight polycomes. Devenight receipt was a second and priority overnight polycomes. Drop Ship miscellaneous fees billed: Days of week overnight is available: Days of week overnight is available: Days of week overnight is available: Drop Ship miscellaneous fees billed: Drop Ship misc
a. EDI b. Autofax c. Fax d. Phone only e. Supplier Web Site only Site Address: Shipping lead time of PO: Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt: Ships regular ground for 3-10 days receipt: Ships regular ground for 3-10 days receipt:
c. Fax d. Phone only e. Supplier Web Site only Site Address: Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone: Expedited Freight Charges or Other Designated Drop Ship Fees: Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Drop Ship miscellaneou
d. Phone only e. Supplier Web Site only Site Address: Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone: Expedited Freight Charges or Other Designated Drop Ship Fees: Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Drop Ship miscellaneous fees
e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone: Expedited Freight Charges or Other Designated Drop Ship Fees: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Drop Ship miscellaneous fees billed: Comments: Ships same day for next day receipt: Ships regular ground for 3-10 days receipt: Ships regular
Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone: Expedited Freight Charges or Other Designated Drop Ship Fees: Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments: Ships for second day receipt: Ships regular ground for 3-10 days receipt: Ships regular ground for 3-10 days receipt: Overnight and Priority Overnight PO Processing Overnight receipt available: PO Receipt cut off time: Days of week overnight is available: Tuesday
Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone: Ships regular ground for 3-10 days receipt: Ships regular ground for 3-10 days receipt: Overnight and Priority Overnight PO Processing Expedited Freight Charges or Other Designated Drop Ship Fees: Overnight receipt available: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Drop Ship miscellaneous fees billed: Days of week overnight is available: Days of week overnight is available: Tuesday
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: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed:
Phone: Expedited Freight Charges or Other Designated Drop Ship Fees: Overnight and Priority Overnight PO Processing Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed:
Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments: Dovernight receipt available: PO Receipt cut off time: Days of week overnight is available: Tuesday
Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments: Dovernight receipt available: PO Receipt cut off time: Days of week overnight is available: Tuesday
Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments: Drop Ship service fee billed with each order: Days of week overnight is available: Tuesday
Drop Ship miscellaneous fees billed: Comments: Days of week overnight is available: Monday Tuesday
Comments: Tuesday
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 Restricted to retail pharmacy only: Saturday Overnight receipt available: PO Receipt Cut off time:
Department to hoppital clinics and physician offices only
Restricted to hospital, clinics, and physician offices only. Restricted from US territories? (explain in comments) Order receipt method: Fax: Friorie #. Fax: Friorie #. 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 #
Physician/Clinic DEA #: Special regulations or returns requirements for this product in certain states?
Physician/Clinic Specialty: If so, which states? Other requirements? Comments?
Miscellaneous Notes:
ADDITIONAL INFORMATION
ADDITIONAL INFORMATION Is product order for scheduled patient procedure?