

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

Version 2021						Introduction ¹	Туре:	New Item		Final Version			Date:	4/10/	2024	
PRODUCT INFORMATION								SPECIAL HANDLING AND STOR			AGE REQUIREMENTS*					
Company Name: SOLA Pharmaceuticals Application: ANDA									a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/AN		perature Range	Controlled Room		and 25 C (68	3° – 77° F)										
Medical Device Class, if applicable:																
DUNS:	080121345								Othe	er Temperature Range	Requirement					
Proprietary Name (If Applicable) a		ame: K		Ophthalmic Solution 0	.5% 5mL					(write in)						
Selling Unit NDC:	70512-790-05			Jse NDC:		UPC: MVX Code:	37051279	90059	Note	es						
""	CVX Code:											_				
Description: Ketorolac Tromethamine Solution/Drops; Ophthalmic 0.5%										is product to be shippe				No No		
Active Ingredient(s): Ketorolac Tromethamine										is product to be shippe	a to customers on c	ify ice?		INO	i .	
/ tours mground(e).	b. Contact for tem	perature excursion qu	estions:													
URL for Additional Product Information:									Name:							
Address:	655 Highlandia D	r.	State:	Address 2:				Number:			866-747-7365					
City:	Baton Rouge					LA	LA Zip: 70810 info@solameds.us			Group E-mail: <u>info@solameds.us</u>						
Key Contact: Phone Number:	866-747-7365	48				800-754-9550	<u>as.us</u>		c Special regulation	one for product in any			No			
Product Therapeutic Classificatio		Nonsteroidal Anti-inflammatory Drug (NSAID)				800-734-9330			c. Special regulations for product in any states? Special returns requirements for this product?			_		No		
Froduct Therapeutic Classificatio	on.	Nonsteroidal A	unu-innaminatory Drug	NOAID)					- Spe	ciai returns requiremen	is for this product?			NO	l .	
	ADDITI	ONAL PRODUC	T INFORMATION			PRODUCT.	DESCRIPT	ION INFORMATION	d. Store product ()	ınit of sale) upright?				Yes		
The product is?			Is the Produc	t Direct-Shi	o Only					tect product (unit of s	ale) from light?			Yes		
a legend device?		No	Is the Produc			C 1	5m	nL	e. Shelf life:	p. oaaot (amt 01 5	, ligilti			24	Months	
if yes, enter class #			Orphan Drug			Size:				al shelf life at launch	if different):				Months	
a product kit?		No				Strength:	0.5	5%								
if yes, list NDCs of			FDA Approva	I Status							ORDER INFORM	MATION				
component parts reverse numbered?		No				Dosage For	m: So	olution/Drops	Unit	of Sale		What is the	NDC selling	unit?		
co-licensed?		No	Allergens Pre	sent						x Bottle		1 Bottle	NDC Selling	unit		
latex-free?		Yes	7.110. go.10 1 10			Don't set Ob.				Box/Carton			g. 1 Box of 1	0 Vials)		
preservative-free?		Yes				Product Sha	ape:			Ampule			•	,		
correctional institution block?		No				Product Col	lor:			Glass		Minimum o	rder quantity	/?	Yes	
opioid?		No								Tube						
Cannabinoid?	it daaa faa	No	Country of Ori	gin India		Product Imp	print:			Vial Liquid Sgl Vial Liquid Multi		If Voc. how	many of whi	ich package t	tumo?	
If Unit Dose, is item bar coded to unhospital scanning?	unit dose for		Is this product	covered under the						Vial Powder Sql			Each	сп раскаде т	yper	
If Unit Dose, indicate NDC here:				ents Act (TAA)?	No					Vial Power Multi			Inner/Cartor	1/Pack		
										Other: Write In			Case			
			FOR GENERIC	DRUG PRODUCTS												
												/ B. I				
					uthorized Generic	orized Generic *If Authorized Generic, other section fields are not applicable			PHARMACY ORDER / BILL UNIT							
I. Orange Book Rating:					section neius are not applicable			Rec. sell unit to cu	Rx billing unit to pharmacy:							
II. Generic Equivalent to What Brand?: ACULAR®							1 Bottle (Write-in, e.g. 1 Vial)					X	Each Gram			
		DRUG SI	JPPLY CHAIN SECUR	ITY ACT (DSCSA) INF	ORMATION				(write-in, e.g. 1 via	11)			Milliliter			
				(/												
Does supplier meet DSCSA defini		rer?	Yes		GLN:	0370512000004				ITEN	I AND PACKING II	NFORMATIO	N			
Is product exempt from DSCSA?			No													
If yes, select exemption:					GCP:	0370512				Weight Lbs.		ons (US msn	•	Volume	Saleable #	
Other exemption - Write in:			Na							110.g.n. 230.	Depth	Width	Height	(Cube)	Pieces	
Is product repackaged? Is product sold by manufacturer's	e avelueiva dietrib	utor?	No No		If yes, was of	original product pur	rcnased		Item/Each:	0.056	1.4567	1.378	2.7953	5.6110968	1	
Has FDA granted waiver/exceptio			No			rce manufacturer f	or repacka	ged product	Box/Carton/Bundle	e/						
If yes, attach documentation from									Inner Pack:					0		
									Case:	3.1288	9.0551	5.7087	6.1024	315.45044	48	
			GTIN AND HIBCC PE	ODUCT INFORMATIO	N					0.1200	0.0001	0.7007	0.1021	010:10011		
Saleable Unit of Measure	,	Salaabla Ous :: 414	LUDGG		0.7	TINI 44		Init of Line CTIN 44	Pallet:	593.184	48	40	47.44	91084.8	8640	
x Item/Each	8	Saleable Quantity	y HIBCC			TN-14 370512790059		Unit of Use GTIN-14 00370512790059								
Box/Carton/Bundle/Inner Pack	1 00370312790039					COST INFORMATION WHOLESALER USE ONL					Y:					
X Case	48 50370512790054															
Pallet									Regular Cost			Vendor #:				
									Invoice Cost (WAC	S) (\$)	\$6.00	Whsl. Code				
	_								As of data:	2/14/2025		Fineline Co	de:			
	-								As of date:	2/14/2020						
i e			Attach copy of S	AFETY DATA SHEET (SDS) or non haz	ard letter, PACKAGE	E INSERT. I	LABEL AND PHOTO OF	PRODUCT PACKAGIN	G and BARCODE.						
*Please provide any additional inf	formation on nago	2	.,					d Dron Shin Only	Sign	nature:						



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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 Comments:

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.

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing						
Purchase orders may be accepted by: a. EDI b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	Purchase order daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:						
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: Comments:	Overnight receipt available: PO Receipt cut off time: Days of week overnight is available: Monday 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 Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:						
Other Data Information Required to Process PO:	Return Instructions						
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty: Miscellaneous Notes:	Contact # if product is received damaged: Is product returnable for credit: URL/Link to returns policy: Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?						
	ADDITIONAL INFORMATION						
	Is product order for scheduled patient procedure? Is product order for restocking purposes?						