

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

Version 2021						Introduction Typ	e: New Item		Final Version			Date:	4/10/	2024
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	RAGE REQUI	REMENTS*		
Company Name: SOLA Pharmaceuticals Application: ANDA								a. Temperature – Indicate the USP temperature range for this product.						
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): A218204 Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)														
Medical Device Class, if applica														
DUNS:	080121345								Other Temperature Range F	Requirement				
Proprietary Name (If Applicable) a		ame: Ketor	olac Tromethamine Ophthaln	nic Solution 0.5	% 10mL				(write in)					
Selling Unit NDC:	70512-790-10		Unit of Use NDC:				70512790103	N	lotes					
UDI			CVX Code:			MVX Code:								
Description:	Ketorolac Trome	thamine Solution/Dro	ps; Ophthalmic 0.5%					ls ls	s this product to be shipped	d to customers on i	ice?		No	
									s this product to be shipped	d to customers on o	dry ice?		No	
Active Ingredient(s): Ketorolac Tromethamine														
									emperature excursion que	estions:				
URL for Additional Product Inform Address:		\ <u></u>				Address 2:			lame:		866-747-736	25		
City:	655 Highlandia D Baton Rouge	л.			State:		Zip: 70810		lumber: Group E-mail:					
Key Contact:	Daton Rouge				Email:	info@solameds.u		Group E-mail: info@solameds.us						
Phone Number:	866-747-7365				Fax:	800-754-9550	<u></u>	c. Special regul	ations for product in any	states?			No	
Product Therapeutic Classification		Nonsteroidal Anti-i	inflammatory Drug (NSAID)						Special returns requirement				No	
l rouge merupaus succinous			, ( ,						poolal rotal no roquilonion	o for tino product.				i .
	ADDIT	IONAL PRODUCT IN	NFORMATION			PRODUCT DES	SCRIPTION INFORMATION	d. Store produc	t (unit of sale) upright?				Yes	1
The product is?			Is the Product	Direct-Ship C	nlv				Protect product (unit of sa	ale) from light?			Yes	Í
a legend device?		No	Is the Product	Unit of Use	,		10mL	e. Shelf life:	. C. Cot product (unit 0) Sc	, irom light:			24	Months
if yes, enter class #			Orphan Drug Status			Size:			nitial shelf life at launch (	if different):				Months
a product kit?		No				Ctura manths	0.5%		· · · · · · · · · · · · · · · · · · ·	,				1
if yes, list NDCs of			FDA Approval Status			Strength:				ORDER INFORM	MATION			
component parts						Dosage Form:	Solution/Drops							
reverse numbered?		No				Dosage Form.			Init of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						x Bottle		1 Bottle			
latex-free?		Yes				Product Shape:	:		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free? correctional institution block?		Yes						-	Ampule Glass		Minimum	rdor augntiti		Yes
opioid?		No No				Product Color:			Tube		Minimum o	ruer quantity	/ f	res
Cannabinoid?		No	Country of Origin	India					Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for	.10	Country of Origin			Product Imprint	t:		Vial Liquid Multi		If Yes, how	many of whi	ich package t	type?
hospital scanning?			Is this product covered u	nder the				' II -	Vial Powder Sql			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (	ΓAA)?	No				Vial Power Multi			Inner/Cartor	n/Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
					Au		Authorized Generic, other		PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating: AT				Se	ection fields are not applicable	Rec. sell unit to customer?			Rx billing u	Rx billing unit to pharmacy:				
II. Generic Equivalent to What Bra	and?:	ACULAR®							1 Bottle		x	Each		
				20004				(Write-in, e.g. 1	Vial)			Gram		
		DRUG SUPP	LY CHAIN SECURITY ACT (	DSCSA) INFO	RMATION							Milliliter		
Does supplier meet DSCSA defin	ition of manufactu	ıror?	Yes		GLN:	0370512000004			ITEN	I AND PACKING I	NEORMATIO	N		
Is product exempt from DSCSA?		iiei:	No	-	GLIN.	0370312000004			***	TAND TACKING T	III OIIIIATIO			
			***		CCD.	0270542				Dimens	ions (US msn	nte \	Valor	Calactic "
If yes, select exemption: Other exemption - Write in:					GCP:	0370512			Weight Lbs.	Dimens	ions (US msn Width	•	Volume (Cube)	Saleable # Pieces
Is product repackaged?			No		If yes was a	riginal product purcha	haze	Item/Each:				Height		
Is product sold by manufacturer's	s exclusive distrib	utor?	No	_	direct from n		iseu	item/Lacii.	0.0613	1.4567	1.378	2.7953	5.6110968	1
Has FDA granted waiver/exception			No			rce manufacturer for re	epackaged product	Box/Carton/Bur	ndle/				_	
If yes, attach documentation fro								Inner Pack:					0	
								Case:	3.3819	9.0551	5.7087	6.1024	315.45044	48
		GT	IN AND HIBCC PRODUCT I	NFORMATION					0.0010	0.0001	0.7007	0.1024	010.40044	40
								Pallet:	638,742	48	40	47.44	91084.8	8640
Saleable Unit of Measure	;	Saleable Quantity	HIBCC			IN-14	Unit of Use GTIN-14							
X Item/Each					00370512790103			WHOLESALER USE ONLY:						
Box/Carton/Bundle/Inner Pack  X Case		48			E03	370512790108			COST INFORMATION			WHOLESAL	LK USE UNL	
X Case		40			303	310012100100		Regular Cost			Vendor #:			
T direct								Invoice Cost (W	/AC) (\$)	\$12.00	Whsl. Code	#:		
									, 117	Ų.2.00	Fineline Co			
								1.1						
								As of date:	2/14/2025					
								As of date:	2/14/2025					
			Attach copy of SAFETY DA	ATA SHEET (SI	OS) or non haza		SERT, LABEL AND PHOTO OF							



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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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#### Version 2021

### 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?						