

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

						Introduction Type:	New Item		Final Version			Date:	10/23	/2025
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	AGE REQUI	REMENTS*		
Company Name: SOLA Pharmaceuticals Application: NDA							NDA	a. Temperature – Indicate the USP temperature range for this product.						
Application Number for NDA/AN	IDA/BLA; PMA/510	(k): 217927				NDA 505(b) Type:	<u>'</u>		mperature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applical	ble:													
DUNS:	080121345							Ot	her Temperature Range F	Requirement				
Proprietary Name (If Applicable) a		ame: Coxanto	Oxaprozin Capsules 300	mg					(write in)					
Selling Unit NDC:	70512-814-60		Unit of Use NDC:		70512-814-60		12814608	No	otes					
UDI			CVX Code:			MVX Code:								
Description:	Coxanto Oxaproz	in Capsules 300 mg 60	ıct					Is	this product to be shipped	d to customers on i	ce?		No	
	·	· -						Is	this product to be shipped	to customers on c	Iry ice?		No	
Active Ingredient(s):		Oxaprozin												
									mperature excursion qu	estions:				
URL for Additional Product Inform									ame:		000 747 704	-		
Address:	655 Highlandia D Baton Rouge	r.			State:	Address 2:	70010		ımber:		866-747-736			
City:	baton Rouge				Email:	info@solameds.us	70810	Gr	oup E-mail:		info@sola	meas.us		
Key Contact: Phone Number:	866-747-7365				Fax:	800-754-9550		c Special regula	tions for product in any	etatoe?			No	
Product Therapeutic Classificatio		Noneteroidal anti-infla	ammatory drugs (NSAIDs)		- Luxi	000-104-3000			pecial returns requirement				No	
Froduct Therapediic Classificatio	111.	Nonsteroldar anti-inne	animatory drugs (NOAIDS)					٥,	beciai returns requirement	s for this product?			INU	
	ADDITI	ONAL PRODUCT INFO	ORMATION			PRODUCT DESC	RIPTION INFORMATION	d Store product	(unit of sale) upright?				No	
The area depth in O	ADDITI	ONALT RODOUT INT		Direct-Ship (Omles.	T ROBOUT BEUG	INIT HOW IN CHAIRMAN	1 I		I-) 6 111-40			No	
The product is?		NI.	Is the Product	Neither	Jnly		60ct	e. Shelf life:	otect product (unit of sa	ile) from light?				Mantha
a legend device? if yes, enter class #		No	Is the Product Orphan Drug Status	Neithei		Size:	6001		itial shelf life at launch (if different):			24	Months Months
a product kit?		No	Orphan Drug Status				300mg		iuai Sileii iile at iaulicii (ii uillereilt).				WOILLIS
if yes, list NDCs of		140	FDA Approval Status			Strength:	ocomg			ORDER INFORM	IATION			
component parts							Capsule; Oral							
reverse numbered?		No				Dosage Form:	•	Ur	nit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						X Bottle		1 Bottle			
latex-free?		Yes				Product Shape:	Oblong capsule		Box/Carton		(Write-in, e.	g. 1 Box of 10	Vials)	
preservative-free?		No				i roddet onape.			Ampule					
correctional institution block?		No				Product Color:	White opaque		Glass		Minimum o	der quantity	?	Yes
opioid?		No							Tube					
Cannabinoid?		No N/A	Country of Origin	United State	S	Product Imprint:	403		Vial Liquid Sgl Vial Liquid Multi		W.V 1			
If Unit Dose, is item bar coded to unhospital scanning?	unit dose for	N/A No	In this product account	and an the a					Vial Liquid Multi Vial Powder Sql			many of whi	сп раскаде і	ype?
If Unit Dose, indicate NDC here:		INO	Is this product covered un Trade Agreements Act (Yes				Vial Powder Sqi Vial Power Multi		12	Inner/Carton	Dook	
ii Oliit Dose, ilidicate NDC liele.			riddo rigi odinonio ridi (.,	163				Other: Write In		1	Case	I ack	
						ļ		_				1 -		
			FOR GENERIC DRUG PR	ODUCTS										
		l	FOR GENERIC DRUG PR	ODUCTS				-						
			FOR GENERIC DRUG PR	ODUCTS	Au	thorized Generic *If A	uthorized Generic, other		PH	ARMACY ORDER	/ BILL UNIT			
L Oranga Book Rating	ΔR		FOR GENERIC DRUG PR	ODUCTS	Au		uthorized Generic, other on fields are not applicable	Rec sell unit to		ARMACY ORDER		nit to pharms	ich.	
I. Orange Book Rating:	AB		FOR GENERIC DRUG PR	ODUCTS	Au			Rec. sell unit to o	customer?	ARMACY ORDER		nit to pharma	су:	
I. Orange Book Rating: II. Generic Equivalent to What Bra			FOR GENERIC DRUG PR	ODUCTS	Au			1 Bo	customer? ottle of 60Ct	ARMACY ORDER	Rx billing u	Each	cy:	
			FOR GENERIC DRUG PR					1 Bo (Write-in, e.g. 1 V	customer? ottle of 60Ct	ARMACY ORDER	Rx billing u		су:	
								1 Bo	customer? ottle of 60Ct (rial)]	Rx billing u	Each Gram Milliliter	icy:	
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II. Generic Equivalent to What Bra Does supplier meet DSCSA defini Is product exempt from DSCSA?	and?:	DRUG SUPPLY	CHAIN SECURITY ACT (RMATION GLN:	0370512000004		1 Bo (Write-in, e.g. 1 V	customer? ottle of 60Ct (rial)	I AND PACKING I	Rx billing u	Each Gram Milliliter		Saleable #
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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 Organic Corrosive Is the product a CA Prop 65 reproductive toxicant? Inorganic Oxidizer No Does the product label bear a CA Prop 65 warning? No Steroid/Androgen 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? c. DOT Hazard Class If Yes, is it managed with a pharmacy registry? 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 2024

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 #:	Fax Number: Fax Number: Phone No.: Site Address: 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 Cha	rges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing					
Expedited freight fees billed with each orde		Overnight receipt available:					
Drop Ship service fee billed with each order Drop Ship miscellaneous fees billed: Comments:	r:	PO Receipt cut off time: Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday					
		Priority Overnight receipt available:					
No restriction: Select YES if sold to retail ph Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician Restricted from US territories? (explain in c Comments:	omments)	PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:					
Other Data Inf	ormation Required to Process PO:	Return Instructions					
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:	fiscellaneous 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?					