



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

Version 2024

Introduction Type: New Item Final Version

Date: 12/2/2025

PRODUCT INFORMATION						SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: SOLA Pharmaceuticals			Application: NDA			a. Temperature – Indicate the USP temperature range for this product.			
Application Number for NDA/ANDA/BLA; PMA/510(k): 217927			NDA 505(b) Type:			Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)			
Medical Device Class, if applicable:						Other Temperature Range Requirement (write in)			
DUNS: 080121345						Notes			
Proprietary Name (If Applicable) and Established Name: Coxanto™ Oxaprozin Capsules 300mg 60ct						Is this product to be shipped to customers on ice?			
Selling Unit NDC: 70512-787-60			Unit of Use NDC: CVX Code:			Is this product to be shipped to customers on dry ice?			
UDI			UPC: 370512787608			No			
Description: Oxaprozin Capsules 300mg 60ct						No			
Active Ingredient(s): Oxaprozin						b. Contact for temperature excursion questions:			
URL for Additional Product Information:						Name: 866-747-7365			
Address: 655 Highlandia Dr.						Number: info@solameds.us			
City: Baton Rouge						Group E-mail:			
Key Contact:						c. Special regulations for product in any states?			
Phone Number: 866-747-7365						Special returns requirements for this product?			
Product Therapeutic Classification: Non-steroidal anti-inflammatory drug (NSAID)						No			
d. Store product (unit of sale) upright?						No			
e. Shelf life: Initial shelf life at launch (if different):						No			
24 Months						24 Months			
ADDITIONAL PRODUCT INFORMATION									
The product is?			Is the Product... Direct-Ship Only			PRODUCT DESCRIPTION INFORMATION			
a legend device?			Is the Product... Neither			Size: 60ct			
if yes, enter class #			Orphan Drug Status			Strength: 300mg			
a product kit?			FDA Approval Status			Dosage Form: Capsule; Oral			
if yes, list NDCs of component parts			Allergens Present			Product Shape: Capsule			
reverse numbered?			Country of Origin United States			Product Color: White			
co-licensed?			Is this product covered under the Trade Agreements Act (TAA)? No			Product Imprint: 403			
latex-free?									
preservative-free?									
correctional institution block?									
opioid?									
Cannabinoid?									
If Unit Dose, is item bar coded to unit dose for hospital scanning?									
If Unit Dose, indicate NDC here:									
FOR GENERIC DRUG PRODUCTS									
I. Orange Book Rating:			Authorized Generic			*If Authorized Generic, other section fields are not applicable			
II. Generic Equivalent to What Brand?: Coxanto									
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION									
Does supplier meet DSCSA definition of manufacturer?			Yes			GLN: 037051200004			
Is product exempt from DSCSA?			No			GCP: 0370512			
If yes, select exemption:						If yes, was original product purchased direct from mfr?			
Other exemption - Write in:						Provide source manufacturer for repackaged product			
Is product repackaged?			No						
Is product sold by manufacturer's exclusive distributor?			No						
Has FDA granted waiver/exception/exemption for product?			No						
If yes, attach documentation from FDA.									
GTIN AND HIBCC PRODUCT INFORMATION									
Saleable Unit of Measure		RFID tag(Y/N)		Saleable Quantity		GTIN-14		Unit of Use GTIN-14	
X Item/Each				12		00370512787608			
X Box/Carton/Bundle/Inner Pack				1		50370512787603			
X Case									
Pallet									
COST INFORMATION									
Regular Cost \$2,623.18						WHOLESALER USE ONLY:			
Invoice Cost (WAC) (\$2,098.54)						Vendor #: <input type="text"/>			
As of date: 12/2/2025						Whsl. Code #: <input type="text"/>			
						Fineline Code: <input type="text"/>			
Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.									
See new p. 3 for Designated Drop Ship Only.									
Signature: <input type="text"/>									

*Please provide any additional information on page 2.



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

Version 2024

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

- a. Cytotoxic?
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?
Is the product a CA Prop 65 carcinogen?
- c. Is the product a CA Prop 65 reproductive toxicant?
- d. Does the product label bear a CA Prop 65 warning?

No

No

No

No

No

No

c. Contact Hazard?

- d. Does this product require special clean-up instructions?
(If yes, attach SDS with special instructions.)
- e. Does the product contain DEHP?

No

No

No

No

Is this product regulated for shipment by DOT?
(if yes, answer a-e below and provide SDS)

- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard?

UN/Identification Number
Proper Shipping Name
DOT Hazard Class
Packing Group
Inhalation Hazard?

No

Is this product regulated for shipment by IATA?
(if yes, answer a-e below and provide SDS)

- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard?

UN/Identification Number
Proper Shipping Name
DOT Hazard Class
Packing Group
Inhalation Hazard?

No

Is the product restricted for air shipment? If so, indicate restriction:

- Passenger
- Cargo
- Passager & Cargo

No

Is this a reportable quantity? No

RQ Threshold: No

Is this a marine pollutant? No

Is this product shipped utilizing an authorized DOT exception or Special Permit?

- No (if yes, identify method below)
- Limited Quantity
- Consumer Commodity, ORM-D
- Small Quantity (49 CFR 173.4)
- Special Permit; DOT-SP
- Special Provision (listed in Column 7 of 49 CFR 172.101);
SP#

No

ADD'L STORAGE INFORMATION

Is the Product...

Controlled Substance? No

Controlled Substance Code

Controlled by State(s)? No

Listed Chemical (List I or II) No

ARCOS Reportable? No

If yes, indicate which:

Schedule No. No

Is it a scheduled listed chemical product? No

CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes

Restricted to retail pharmacy only: No

Restricted to hospital, clinics, and physician offices only: No

Restricted from US territories? (explain in comments) No

Comments:

SDS Hazard Classification

- Organic
- Inorganic
- Steroid/Androgen

- Corrosive
- Oxidizer
- Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level:

No

NFPA Storage Level:

Is the product a NIOSH hazardous drug?

No

If yes, indicate which:

Hazardous Waste Identification

EPA Hazardous Waste Code:

Waste Characteristics

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?

No

If Yes, is it managed with a pharmacy registry?

Website URL:

Med Guide Required

Limited Distribution Requirement

Comments / Details: (For example, iPledge program?)

REMS:

REMS Program Manager Name:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name:

Site Enrollment Number assigned by Supplier:

Comments:

Phone:

DEA #:

NCPDP#:

NPI #:

Registry:

Registry Program Contact Name:

Phone:

Comments:

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 866-747-7365

Is product returnable for credit: Yes

URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states?

No

If so, which states? Other requirements? Comments?

MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE

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	
<p>Purchase orders may be accepted by:</p> <p>a. EDI b. Autofax c. Fax d. Phone only e. Supplier Web Site only</p>		<p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:</p>	
<p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: Name: <input type="text"/> Phone: <input type="text"/></p>		Expedited Freight Charges or Other Designated Drop Ship Fees:	
<p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input type="text"/></p>		<p>Overnight and Priority Overnight PO Processing</p> <p>Overnight receipt available: <input type="text"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available: Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday <input type="checkbox"/></p> <p>Priority Overnight receipt available: <input type="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <input type="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: Phone: <input type="text"/> Fax: <input type="text"/> EDI: <input type="text"/></p> <p>Overnight Fees apply: Other fees apply: <input type="text"/></p>	
Class of Trade Restriction:		<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="text"/></p> <p>Comments: <input type="text"/></p>	
Other Data Information Required to Process PO:		<p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="text"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>	
Miscellaneous Notes:		Return Instructions	
ADDITIONAL INFORMATION		<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>	