



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

Version 2024 Introduction Type:  New Item  Final Version Date: 10/23/2025

**PRODUCT INFORMATION**

Company Name: SOLA Pharmaceuticals Application Number for NDA/ANDA/BLA: 217927 Application: NDA NDA 505(b) Type:

Medical Device Class, if applicable:

DUNS: 080121345

Proprietary Name (If Applicable) and Established Name: Coxanto Oxaprozin Capsules 300 mg

Selling Unit NDC: 70512-814-60 Unit of Use NDC: 70512-814-60 UPC: 370512814608

UDI CVX Code: MVX Code:

Description: Coxanto Oxaprozin Capsules 300 mg 60ct

Active Ingredient(s): Oxaprozin

URL for Additional Product Information:

Address: 655 Highlandia Dr. Address 2: State: LA Zip: 70810

City: Baton Rouge Email: [info@solameds.us](mailto:info@solameds.us)

Key Contact: Phone Number: 866-747-7365 Fax: 800-754-9550

Product Therapeutic Classification: Nonsteroidal anti-inflammatory drugs (NSAIDs)

**SPECIAL HANDLING AND STORAGE REQUIREMENTS\***

a. Temperature – Indicate the USP temperature range for this product.  
Temperature Range:  Controlled Room – between 20 and 25 C (68° – 77° F)

Other Temperature Range Requirement (write in):

Notes:

Is this product to be shipped to customers on ice?  No

Is this product to be shipped to customers on dry ice?  No

b. Contact for temperature excursion questions:  
Name:

Number: 866-747-7365

Group E-mail: [info@solameds.us](mailto:info@solameds.us)

c. Special regulations for product in any states?  No  
Special returns requirements for this product?  No

d. Store product (unit of sale) upright?  No  
Protect product (unit of sale) from light?  No

e. Shelf life:  24 Months  
Initial shelf life at launch (if different):  Months

**ADDITIONAL PRODUCT INFORMATION**

The product is?  
a legend device?  No  
if yes, enter class #

if yes, list NDCs of component parts reverse numbered?  No  
co-licensed?  No  
latex-free?  Yes  
preservative-free?  No  
correctional institution block?  No  
opioid?  No  
Cannabinoid?  No

If Unit Dose, is item bar coded to unit dose for hospital scanning?  No  
If Unit Dose, indicate NDC here:

Is the Product...  
Is the Product...  Direct-Ship Only  Neither  
Orphan Drug Status

FDA Approval Status

Allergens Present

Country of Origin  United States

Is this product covered under the Trade Agreements Act (TAA)?  Yes

**PRODUCT DESCRIPTION INFORMATION**

Size: 60ct

Strength: 300mg

Dosage Form: Capsule; Oral

Product Shape: Oblong capsule

Product Color: White opaque

Product Imprint: 403

**ORDER INFORMATION**

Unit of Sale

<input checked="" type="checkbox"/>	Bottle
<input type="checkbox"/>	Box/ Carton
<input type="checkbox"/>	Ampule
<input type="checkbox"/>	Glass
<input type="checkbox"/>	Tube
<input type="checkbox"/>	Vial Liquid Sgl
<input type="checkbox"/>	Vial Liquid Multi
<input type="checkbox"/>	Vial Powder Sgl
<input type="checkbox"/>	Vial Powder Multi
<input type="checkbox"/>	Other: Write In

What is the NDC selling unit?  
 1 Bottle  
(Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity?  Yes

If Yes, how many of which package type?

<input type="text"/>	12	Each
<input type="text"/>		Inner/ Carton/ Pack
<input type="text"/>	1	Case

**FOR GENERIC DRUG PRODUCTS**

I. Orange Book Rating:  AB  Authorized Generic \*If Authorized Generic, other section fields are not applicable

II. Generic Equivalent to What Brand?:

**PHARMACY ORDER / BILL UNIT**

Rec. sell unit to customer?  1 Bottle of 60Ct

Rx billing unit to pharmacy:  1 Each

(Write-in, e.g. 1 Vial)

HCPCS J-Code:

**DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION**

Does supplier meet DSCSA definition of manufacturer?  Yes  No

Is product exempt from DSCSA?  Yes  No

If yes, select exemption:

Other exemption - Write in:

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.

GLN: 0370512000004

GCP: 0370512

If yes, was original product purchased direct from mfr?

Provide source manufacturer for repackaged product

**ITEM AND PACKING INFORMATION**

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Box/ Carton/ Bundle/ Inner Pack:	0.11	2	2	3.5	14	1
Case:	1.473	7 5/8	6 3/8	3 3/4	182 2/7	12
Pallet:	448	40	40	38	60800	3648

**GTIN AND HIBCC PRODUCT INFORMATION**

Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each		1		00370512814601	370512814601
<input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack					
<input checked="" type="checkbox"/> Case		12		50370512814606	
<input type="checkbox"/> Pallet					

**COST INFORMATION**

Regular Cost  \$1,834.80

Invoice Cost (WAC) (\$)  \$1,529.00

As of date: 10/23/2025

**WHOLESALE USE ONLY:**

Vendor #:

Whsl. Code #:

Fineline Code:



# 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?  No
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?
  - Is the product a CA Prop 65 carcinogen?  No
  - Is the product a CA Prop 65 reproductive toxicant?  No
  - Does the product label bear a CA Prop 65 warning?  No

- c. Contact Hazard?  No
- d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)  No
- e. Does the product contain DEHP?  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?  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?  No

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

- Passenger  No
- Cargo  No
- Passenger & Cargo  No

Is this a reportable quantity?  No

RQ Threshold:

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#

### ADD'L STORAGE INFORMATION

Is the Product...

- Controlled Substance?  No  Yes      Controlled Substance Code
- Controlled by State(s)?  No  Yes      Listed Chemical (List I or II)   No
- ARCOS Reportable?  No  Yes      If yes, indicate which:
- Schedule No.       Is it a scheduled listed chemical product?:  No  Yes

### CLASS OF TRADE RESTRICTION:

- No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes  No
- Restricted to retail pharmacy only:  No  Yes
- Restricted to hospital, clinics, and physician offices only:  No  Yes
- Restricted from US territories? (explain in comments)  No  Yes

Comments:

### SDS Hazard Classification

- Organic  Corrosive
- Inorganic  Oxidizer
- Steroid/Androgen  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? If yes, indicate which:  No

### Hazardous Waste Identification

EPA Hazardous Waste Code:  Waste Characteristics:

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?  No  Yes  
If Yes, is it managed with a pharmacy registry?  No  Yes  
Website URL:

Med Guide Required  No  Yes  
Limited Distribution Requirement  No  Yes  
Comments / Details: (For example, iPledge program?)

**REMS:**  No  Yes  
REMS Program Manager Name:  Phone:   
Supplier Manages REMS registry exclusively:  No  Yes  
Wholesale distributor support:  No  Yes  
Provider Name:  DEA #:   
Site Enrollment Number assigned by Supplier:  NCPDP#:   
NPI #:

Comments

**Registry:**  No  Yes  
Registry Program Contact Name:  Phone:   
Comments

### RETURN INSTRUCTIONS

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

Is product returnable for credit:  Yes  No

URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states?  No  Yes

If so, which states? Other requirements? Comments:

### MISCELLANEOUS NOTES and/or Image of Product Barcode:

