



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

Version 2024

Introduction Type: ☐ Final Version

Date:

3/21/2025

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: SOLA Pharmaceuticals				Application: ANDA			
Application Number for NDA/ANDA/BLA; PMA/510(k): 212808				NDA 505(b) Type:			
Medical Device Class, if applicable:							
DUNS: 080121345							
Proprietary Name (If Applicable) and Established Name: Ropivacaine HCl Injection USP 400mg/200mL							
Selling Unit NDC: 70512-798-24				Unit of Use NDC: 70512-798-01		UPC: 370512798017	
UDI				CVX Code:		MXV Code:	
Description: Ropivacaine HCl Injection USP 400mg/200mL							
Active Ingredient(s): Ropivacaine HCl							
URL for Additional Product Information:							
Address: 655 Highlandia Dr.				Address 2:			
City: Baton Rouge				State: LA		Zip: 70810	
Key Contact:				Email: info@solameds.us			
Phone Number: 866-747-7365				Fax: 800-754-9550			
Product Therapeutic Classification: Anesthetic (Local)							
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
The product is?		Is the Product...		Size:		200mL	
a legend device?		Direct-Ship Only					
<input type="checkbox"/> No		<input type="checkbox"/> Neither					
if yes, enter class #		Orphan Drug Status		Strength:		0.20%	
<input type="checkbox"/> No		<input type="checkbox"/>					
if yes, list NDCs of component parts		FDA Approval Status		Dosage Form:		Injection	
<input type="checkbox"/> No		<input type="checkbox"/>					
reverse numbered?		<input type="checkbox"/> No		Product Shape:			
<input type="checkbox"/> No		<input type="checkbox"/> Yes					
co-licensed?		<input type="checkbox"/> No		Product Color:			
<input type="checkbox"/> Yes		<input type="checkbox"/>					
latex-free?		<input type="checkbox"/> No		Product Imprint:			
<input type="checkbox"/> No		<input type="checkbox"/>					
preservative-free?		<input type="checkbox"/> No					
<input type="checkbox"/> No		<input type="checkbox"/>					
correctional institution block?		<input type="checkbox"/> No					
<input type="checkbox"/> No		<input type="checkbox"/>					
opioid?		<input type="checkbox"/> No					
<input type="checkbox"/> No		<input type="checkbox"/>					
Cannabinoid?		<input type="checkbox"/> No					
<input type="checkbox"/> No		<input type="checkbox"/>					
If Unit Dose, is item bar coded to unit dose for hospital scanning?		<input type="checkbox"/>		Country of Origin		India	
<input type="checkbox"/>		<input type="checkbox"/>					
If Unit Dose, indicate NDC here:		<input type="checkbox"/>		Is this product covered under the Trade Agreements Act (TAA)?		<input type="checkbox"/> No	
<input type="checkbox"/>		<input type="checkbox"/>					
FOR GENERIC DRUG PRODUCTS							
I. Orange Book Rating: AP				<input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable			
II. Generic Equivalent to What Brand?: NAROPIN®							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer?				GLN: 0370512000004			
<input type="checkbox"/> Yes							
Is product exempt from DSCSA?				GCP: 0370512			
<input type="checkbox"/> No							
If yes, select exemption:				If yes, was original product purchased direct from mfr?			
<input type="checkbox"/>				<input type="checkbox"/>			
Other exemption - Write in:				Provide source manufacturer for repackaged product			
<input type="checkbox"/>				<input type="checkbox"/>			
Is product sold by manufacturer's exclusive distributor?							
<input type="checkbox"/> No							
Has FDA granted waiver/exception/exemption for product?							
<input type="checkbox"/> No							
If yes, attach documentation from FDA.							
<input type="checkbox"/>							
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		00370512798246	00370512798017	
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack							
<input type="checkbox"/> Case							
<input type="checkbox"/> Pallet							
ITEM AND PACKING INFORMATION							
	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces	
		Depth	Width	Height			
Item/Each:	13.66	14.17	12.59	8.07	1439.6904	1	
Box/ Carton/ Bundle/ Inner Pack:							
Case:							
Pallet:	394.42	47.24	39.37	42.91	79805.683	24	
COST INFORMATION							
Regular Cost				WHOLESALE USE ONLY:			
Invoice Cost (WAC) (\$)				Vendor #:			
				Whsl. Code #:			
As of date: 3/21/2025				Fineline Code:			

*Please provide any additional information on page 2.

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:



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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):

- 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
- ☐ Cargo
- ☐ Passenger & Cargo

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

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 ☐ 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

If Yes, is it managed with a pharmacy registry?

☐ No

Website URL:

Med Guide Required

☐ No

Limited Distribution Requirement

☐ No

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

REMS:

☐ No

REMS Program Manager Name:

Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name:

DEA #:

Site Enrollment Number assigned
by Supplier:

NCPDP#:

NPI #:

Comments

Registry:

☐ No

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



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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
<p>Purchase orders may be accepted by:</p> <p>a. EDI <input type="text"/></p> <p>b. Autofax <input type="text"/></p> <p>c. Fax <input type="text"/></p> <p>d. Phone only <input type="text"/></p> <p>e. Supplier Web Site only <input type="text"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/></p> <p>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Phone No.: <input type="text"/></p> <p>Site Address: <input type="text"/></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: <input type="text"/></p> <p>Ships for second day receipt: <input type="text"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="text"/></p>
<p>Expedited Freight Charges or Other Designated Drop Ship Fees:</p> <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:</p> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</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: <input type="text"/></p> <p>Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="text"/></p> <p>Other fees apply: <input type="text"/></p>
<p>Class of Trade Restriction:</p> <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="text"/></p> <p>Restricted to retail pharmacy only: <input type="text"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="text"/></p> <p>Restricted from US territories? (explain in comments) <input type="text"/></p> <p>Comments: <input type="text"/></p>	
<p>Other Data Information Required to Process PO:</p> <p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p>Return Instructions</p> <p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="text"/></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>
<p>Miscellaneous Notes:</p> <p><input type="text"/></p>	<p>ADDITIONAL INFORMATION</p> <p>Is product order for scheduled patient procedure? <input type="text"/></p> <p>Is product order for restocking purposes? <input type="text"/></p>