



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

Version 2024		Introduction Type: <input type="text"/>		<input type="text"/> Final Version		Date: <input type="text"/> 3/21/2025																																
PRODUCT INFORMATION						SPECIAL HANDLING AND STORAGE REQUIREMENTS*																																
<div>Company Name: SOLA Pharmaceuticals</div> <div>Application Number for NDA/ANDA/BLA; PMA/510(k): 212808</div> <div>Medical Device Class, if applicable:</div> <div>DUNS: 080121345</div> <div>Proprietary Name (If Applicable) and Established Name: Ropivacaine HCl Injection USP 200mg/100mL</div> <div>Selling Unit NDC: 70512-797-24</div> <div>Unit of Use NDC: 70512-797-01</div> <div>UPC: 370512797010</div> <div>CVX Code:</div> <div>MXV Code:</div> <div>Description: Ropivacaine HCl Injection USP 200mg/100mL</div> <div>Active Ingredient(s): Ropivacaine HCl</div> <div>URL for Additional Product Information:</div> <div>Address: 655 Highlandia Dr.</div> <div>City: Baton Rouge</div> <div>Key Contact:</div> <div>Phone Number: 866-747-7365</div> <div>Product Therapeutic Classification: Anesthetic (Local)</div> <div>Application: ANDA</div> <div>NDA 505(b) Type:</div>						<div>a. Temperature – Indicate the USP temperature range for this product.</div> <div>Temperature Range: <input type="text"/> Controlled Room – between 20 and 25 C (68° – 77° F)</div> <div>Other Temperature Range Requirement (write in):</div> <div>Notes:</div> <div>Is this product to be shipped to customers on ice? <input type="text"/> No</div> <div>Is this product to be shipped to customers on dry ice? <input type="text"/> No</div> <div>b. Contact for temperature excursion questions:</div> <div>Name:</div> <div>Number: 866-747-7365</div> <div>Group E-mail: info@solameds.us</div> <div>c. Special regulations for product in any states?</div> <div>Special returns requirements for this product? <input type="text"/> No</div> <div>d. Store product (unit of sale) upright?</div> <div>Protect product (unit of sale) from light? <input type="text"/> No</div> <div>e. Shelf life:</div> <div>Initial shelf life at launch (if different): <input type="text"/> 24 Months</div>																																
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION																																		
<div>The product is?</div> <div>a legend device? <input type="text"/> No</div> <div>if yes, enter class #</div> <div>a product kit? <input type="text"/> No</div> <div>if yes, list NDCs of component parts</div> <div>reverse numbered? <input type="text"/> No</div> <div>co-licensed? <input type="text"/> No</div> <div>latex-free? <input type="text"/> Yes</div> <div>preservative-free? <input type="text"/> No</div> <div>correctional institution block? <input type="text"/> No</div> <div>opioid? <input type="text"/> No</div> <div>Cannabinoid? <input type="text"/> No</div> <div>If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="text"/></div> <div>If Unit Dose, indicate NDC here:</div> <div>Is the Product... Direct-Ship Only <input type="text"/> Neither</div> <div>Is the Product... Orphan Drug Status</div> <div>FDA Approval Status</div> <div>Allergens Present</div> <div>Country of Origin: India</div> <div>Is this product covered under the Trade Agreements Act (TAA)? <input type="text"/> No</div> <div>Size: 100mL</div> <div>Strength: 0.20%</div> <div>Dosage Form: Injection</div> <div>Product Shape:</div> <div>Product Color:</div> <div>Product Imprint:</div>																																						
FOR GENERIC DRUG PRODUCTS						ORDER INFORMATION																																
<div>I. Orange Book Rating: AP</div> <div>II. Generic Equivalent to What Brand?: NAROPIN®</div> <div>Authorized Generic <input type="checkbox"/> *If Authorized Generic, other section fields are not applicable</div>						<div>Unit of Sale</div> <div><input checked="" type="checkbox"/> Bottle</div> <div><input type="checkbox"/> Box/Carton</div> <div><input type="checkbox"/> Ampule</div> <div><input type="checkbox"/> Glass</div> <div><input type="checkbox"/> Tube</div> <div><input type="checkbox"/> Vial Liquid Sgl</div> <div><input type="checkbox"/> Vial Liquid Multi</div> <div><input type="checkbox"/> Vial Powder Sgl</div> <div><input type="checkbox"/> Vial Powder Multi</div> <div><input type="checkbox"/> Other: Write In</div> <div>What is the NDC selling unit?</div> <div>1 Case of 24 Bags</div> <div>(Write-in, e.g. 1 Box of 10 Vials)</div> <div>Minimum order quantity? <input type="text"/> Yes</div> <div>If Yes, how many of which package type?</div> <div><input type="text"/> 1 Each</div> <div><input type="text"/> Inner/Carton/Pack</div> <div><input type="text"/> Case</div>																																
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION						PHARMACY ORDER / BILL UNIT																																
<div>Does supplier meet DSCSA definition of manufacturer? <input type="text"/> Yes</div> <div>Is product exempt from DSCSA? <input type="text"/> No</div> <div>If yes, select exemption:</div> <div>Other exemption - Write in:</div> <div>Is product repackaged? <input type="text"/> No</div> <div>Is product sold by manufacturer's exclusive distributor? <input type="text"/> No</div> <div>Has FDA granted waiver/exception/exemption for product? <input type="text"/> No</div> <div>If yes, attach documentation from FDA.</div> <div>GLN: 0370512000004</div> <div>GCP: 0370512</div> <div>If yes, was original product purchased direct from mfr? <input type="text"/></div> <div>Provide source manufacturer for repackaged product</div>						<div>Rec. sell unit to customer?</div> <div>1 Each; 24 bags</div> <div>(Write-in, e.g. 1 Vial)</div> <div>HCPCS J-Code:</div> <div>Rx billing unit to pharmacy:</div> <div><input type="text"/> 1 Each</div> <div><input type="text"/> Gram</div> <div><input type="text"/> Milliliter</div>																																
GTIN AND HIBCC PRODUCT INFORMATION						ITEM AND PACKING INFORMATION																																
<div>Saleable Unit of Measure</div> <div>RFID tag(Y/N)</div> <div>Saleable Quantity</div> <div>HIBCC</div> <div>GTIN-14</div> <div>Unit of Use GTIN-14</div> <div><input checked="" type="checkbox"/> Item/Each</div> <div><input type="checkbox"/> Box/Carton/Bundle/Inner Pack</div> <div><input type="checkbox"/> Case</div> <div><input type="checkbox"/> Pallet</div> <div><input type="text"/> 1</div> <div><input type="text"/></div> <div><input type="text"/></div> <div><input type="text"/></div> <div><input type="text"/></div> <div><input type="text"/></div>						<table border="1" style="width:100%; border-collapse: collapse;"><thead><tr><th rowspan="2">Item/Each:</th><th rowspan="2">Weight Lbs.</th><th colspan="3">Dimensions (US msmts.)</th><th rowspan="2">Volume (Cube)</th><th rowspan="2">Saleable # Pieces</th></tr><tr><th>Depth</th><th>Width</th><th>Height</th></tr></thead><tbody><tr><td>Box/Carton/Bundle/Inner Pack:</td><td>8.15</td><td>11.22</td><td>10.62</td><td>5.31</td><td>632.72048</td><td>1</td></tr><tr><td>Case:</td><td></td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>Pallet:</td><td>659.45</td><td>47.24</td><td>39.37</td><td>44.88</td><td>83469.565</td><td>72</td></tr></tbody></table>		Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces	Depth	Width	Height	Box/Carton/Bundle/Inner Pack:	8.15	11.22	10.62	5.31	632.72048	1	Case:							Pallet:	659.45	47.24	39.37	44.88	83469.565	72
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COST INFORMATION						WHOLESALE USE ONLY:																																
<div>Regular Cost</div> <div>Invoice Cost (WAC) (\$)</div> <div>As of date: 3/21/2025</div> <div>\$576.00</div>						<div>Vendor #:</div> <div>Whsl. Code #:</div> <div>Fineline Code:</div>																																
<div>*Please provide any additional information on page 2.</div> <div>Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.</div> <div>See new p. 3 for Designated Drop Ship Only.</div> <div>Signature: <input type="text"/></div>																																						



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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

NCPDP#:

by Supplier:

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>