



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

Version 2021 Introduction Type: New Item Final Version Date: 1/26/2023

PRODUCT INFORMATION

Company Name: SOLA Pharmaceuticals **Application:**

Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):

Medical Device Class, if applicable:

DUNS: 080121345

Proprietary Name (if Applicable) and Established Name:

Selling Unit NDC: 70512-017-15 **Unit of Use NDC:** **UPC:** 370512017156

UDI **CVX Code:** **MXV Code:**

Description: Lidocaine/Menthol/Methyl Salicylate topical patch; 15 patches

Active Ingredient(s): Lidocaine 4%, Menthol 1%, Methyl Salicylate 2%

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:

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.

Temperature Range:

Other Temperature Range Requirement (write in):

Notes: Avoid storing product in direct sunlight; protect product from excessive moisture.

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

c. Special regulations for product in any states?

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:

Initial shelf life at launch (if different): Months

ADDITIONAL PRODUCT INFORMATION

The product is a legend device? No

If yes, enter class # a product kit? No

If yes, list NDCs of component parts reverse numbered? No

co-licensed? No

latex-free? Yes

preservative-free? Yes

correctional institution block? No

opioid? No

Cannabinoid? No

If Unit Dose, is item bar coded to unit dose for hospital scanning?

If Unit Dose, indicate NDC here:

Is the Product... Direct-Ship Only

Is the Product... Orphan Drug Status

FDA Approval Status

Allergens Present

Country of Origin

Is this product covered under the Trade Agreements Act (TAA)? No

Size: 15 patches

Strength: Lidocaine 4%, Menthol 1%

Dosage Form: Topical Patch

Product Shape: Rectangle

Product Color:

Product Imprint:

ORDER INFORMATION

Unit of Sale

Bottle

Box/Carton

Ampule

Glass

Tube

Vial Liquid Sgl

Vial Liquid Multi

Vial Powder Sgl

Vial Power Multi

Other: Write In

What is the NDC selling unit? 1 box of 15 patches (Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity? Yes

If Yes, how many of which package type?

Each

Inner/Carton/Pack

Case

FOR GENERIC DRUG PRODUCTS

Authorized Generic *If Authorized Generic, other section fields are not applicable

I. Orange Book Rating:

II. Generic Equivalent to What Brand?:

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer? (Write-in, e.g. 1 Vial)

Rx billing unit to pharmacy:

Each

Gram

Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? Yes

Is product exempt from DSCSA? Yes

If yes, select exemption: Other exemption: (Write in)

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:	0.5125	0.19685	5.51181	7.59843	8.244295	1
Case:	12.3	23.5	15.5	6	2185.5	24
Pallet:	332.9	47	31.5	44	65142	552

GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each				
<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack	1		00370512017156	
<input checked="" type="checkbox"/> Case	24		50370512017151	
<input type="checkbox"/> Pallet				

COST INFORMATION

Regular Cost

Invoice Cost (WAC) (\$) \$659.95

As of date: 3/22/2023

WHOLESALE USE ONLY:

Vendor #:

Whsl. Code #:

Fineline Code: