

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

Version 2021

Introduction Type: New Item

Final Version

Date: 8/24/2022

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: Lidaflex- Lidocaine Patch

Selling Unit NDC: 70512-012-30 Unit of Use NDC: 70512-012-30 UPC: 077512012303

UDI:

CVX Code:

MVX Code:

Description: Lidaflex Topical Patch; Lidocaine 4% patch; 30ct

Active Ingredient(s): Lidocaine 4%

URL for Additional Product Information:

Address: 655 Highlandia Dr. City: Baton Rouge State: LA Address 2: Zip: 70810

Key Contact: Email: info@solameds.us

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

Product Therapeutic Classification: Topical Anesthetic

ADDITIONAL PRODUCT INFORMATION	PRODUCT DESCRIPTION INFORMATION
The product is? <input type="checkbox"/> No a legend device? if yes, enter class # <input type="text"/> if yes, list NDCs of component parts reverse numbered? <input type="checkbox"/> No co-licensed? <input type="checkbox"/> No latex-free? <input type="checkbox"/> Yes preservative-free? <input type="checkbox"/> Yes correctional institution block? <input type="checkbox"/> No opioid? <input type="checkbox"/> No Cannabinoid? <input type="checkbox"/> No If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/> No If Unit Dose, indicate NDC here: <input type="text"/>	Is the Product... <input type="checkbox"/> Direct-Ship Only Is the Product... <input type="checkbox"/> Unit of Use Orphan Drug Status <input type="checkbox"/> FDA Approval Status <input type="text"/> Allergens Present <input type="text"/> Country of Origin <input type="text"/> USA Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/>
	Size: 30 patches Strength: 4% Dosage Form: Topical patch Product Shape: Rectangle topical patch Product Color: White Product Imprint: <input type="text"/>

SPECIAL HANDLING AND STORAGE REQUIREMENTS

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

Temperature Range:

Other Temperature Range Requirement (write in): Store at room temperature.

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? 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

ORDER INFORMATION

Unit of Sale <input checked="" type="checkbox"/> Bottle <input checked="" 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 Power Multi <input type="checkbox"/> Other: Write In <input type="text"/>	What is the NDC selling unit? 1 box of 30 patches (Write-in, e.g. 1 Box of 10 Vials) Minimum order quantity? <input type="checkbox"/> Yes If Yes, how many of which package type? 24 Each Inner/ Carton/Pack Case
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FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating:

II. Generic Equivalent to What Brand?:

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

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer? 1 box
 (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: OTC exemption

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: 370512000004

GPC:

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:	0.41	1	6.5	5.75	37.375	1
Case:	9.65	13.5	7.5	12.5	1265.625	24
Pallet:	607.95	40.5	37.5	52.5	79734.375	1512

GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
Item/Each	1		00370512012304	
X Box/Carton/Bundle/Inner Pack	24		50370512012309	
X Case				
Pallet				

COST INFORMATION

Regular Cost

Invoice Cost (WAC) (\$) \$32.66

As of date: 8/24/22

WHOLESALE USE ONLY:

Vendor #:

Whst. Code #:

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: