



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

Version 2021

Introduction Type: New Item Final Version

Date:

PRODUCT INFORMATION

Company Name: SOLA Pharmaceuticals **Application:** ANDA

Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 206116

Medical Device Class, if applicable:

DUNS: 080121345

Proprietary Name (if Applicable) and Established Name: Diclofenac Sodium Topical Soutlion, 1.5% w/w

Selling Unit NDC: 70512-810-05 **Unit of Use NDC:** **UPC:** 370512810054

UDI **CVX Code:** **MVX Code:**

Description: Diclofenac sodium topical solution 1.5% w/w is supplied as a clear, colorless to faintly pink-orange solution containing 16.05mg of diclofenac sodium per 1 mL of solution

Active Ingredient(s): Diclofenac Sodium

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: Nonsteroidal anti-inflammatory drug (NSAID)

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

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

Temperature Range:

Other Temperature Range Requirement (write in):

Notes:

Is this product to be shipped to customers on ice?

Is this product to be shipped to customers on dry ice?

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?

d. Store product (unit of sale) upright?

Protect product (unit of sale) from light?

e. Shelf life:

Initial shelf life at launch (if different): Months

ADDITIONAL PRODUCT INFORMATION

The product is a legend device?

If yes, enter class # a product kit?

If yes, list NDCs of component parts reverse numbered?

co-licensed?

latex-free?

preservative-free?

correctional institution block?

opioid?

Cannabinoid?

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... Unit of Use

Orphan Drug Status

FDA Approval Status

Allergens Present

Country of Origin

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

PRODUCT DESCRIPTION INFORMATION

Size: 150mL

Strength: 1.50%

Dosage Form: Topical Solution

Product Shape:

Product Color: Clear, colorless to faintly pink-orange solution

Product Imprint:

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 Power Multi
<input type="checkbox"/>	Other: Write In

What is the NDC selling unit?

(Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity?

If Yes, how many of which package type?

<input type="text" value="24"/>	Each
<input type="text"/>	Inner/Carton/Pack
<input type="text"/>	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:

<input checked="" type="checkbox"/>	Each
<input type="checkbox"/>	Gram
<input type="checkbox"/>	Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?

Is product exempt from DSCSA?

If yes, select exemption:

Other exemption - Write in:

Is product repackaged?

Is product sold by manufacturer's exclusive distributor?

Has FDA granted waiver/exception/exemption for product?

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		
Item/Each:	210.07gm	2.625	5.625	1.6875	24.916992	1
Box/Carton/Bundle/Inner Pack:					0	
Case:	11.55	11.1875	6.25	10.875	760.40039	24
Pallet:	733	44.75	36.25	32.625	52923.867	1440

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	1		00370512810054	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	24		50370512810059	
<input type="checkbox"/> Pallet				

COST INFORMATION

Regular Cost

Invoice Cost (WAC) (\$)

As of date:

Vendor #:

Whsl. 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: