

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

Version 2021

Introduction Type:

Final Version

Date: 8/24/2022

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*																															
Company Name: SOLA Pharmaceuticals Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 204132 Medical Device Class, if applicable: DUNS: 080121345 Proprietary Name (if Applicable) and Established Name: Diclofenac Sodium 1.5% Topical Solution, 150ml Selling Unit NDC: 70512-038-05      Unit of Use NDC: 70512-038-05      UPC: 370512038052 UDI:      CVX Code:      MVX Code:				<b>a. Temperature – Indicate the USP temperature range for this product.</b> Temperature Range: _____ Other Temperature Range Requirement (write in): Store at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F). Notes: _____ Is this product to be shipped to customers on ice? <input type="checkbox"/> No Is this product to be shipped to customers on dry ice? <input type="checkbox"/> No																															
Description: Diclofenac Sodium 1.5% Topical Solution, 150ml Active Ingredient(s): Diclofenac Sodium 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: NSAID				<b>b. Contact for temperature excursion questions:</b> Name: _____ Number: 866-747-7365 Group E-mail: info@solameds.us <b>c. Special regulations for product in any states?</b> <input type="checkbox"/> No Special returns requirements for this product? <input type="checkbox"/> No <b>d. Store product (unit of sale) upright?</b> <input type="checkbox"/> Yes Protect product (unit of sale) from light? <input type="checkbox"/> No <b>e. Shelf life:</b> 24 Months Initial shelf life at launch (if different):      _____ Months																															
<b>ADDITIONAL PRODUCT INFORMATION</b> <b>PRODUCT DESCRIPTION INFORMATION</b>				<b>ORDER INFORMATION</b>																															
The product is? a legend device? <input type="checkbox"/> No if yes, enter class # _____ 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: _____		Is the Product... Direct-Ship Only <input type="checkbox"/> _____ Is the Product... Orphan Drug Status <input type="checkbox"/> _____ FDA Approval Status _____ Allergens Present _____ Country of Origin: India		Size: 150mL Strength: 1.5% Dosage Form: Topical solution Product Shape: _____ Product Color: Clear, colorless to faintly pink-orange solution Product Imprint: _____		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? 1 bottle of 150mL (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																													
<b>FOR GENERIC DRUG PRODUCTS</b> I. Orange Book Rating: AT II. Generic Equivalent to What Brand?: Pennsaid®				<b>PHARMACY ORDER / BILL UNIT</b> Rec. sell unit to customer? 1 bottle (Write-in, e.g. 1 Vial) Rx billing unit to pharmacy: <input checked="" type="checkbox"/> Each, <input type="checkbox"/> Gram, <input type="checkbox"/> Milliliter																															
<b>DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION</b> Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/> Yes, <input checked="" type="checkbox"/> No Is product exempt from DSCSA? <input type="checkbox"/> Yes, <input checked="" type="checkbox"/> No If yes, select exemption: _____ Other exemption - Write in: _____ Is product repackaged? <input type="checkbox"/> Yes, <input checked="" type="checkbox"/> No Is product sold by manufacturer's exclusive distributor? <input type="checkbox"/> Yes, <input checked="" type="checkbox"/> No Has FDA granted waiver/exception/exemption for product? <input type="checkbox"/> Yes, <input checked="" type="checkbox"/> No If yes, attach documentation from FDA.				GLN: 370512000004 GCP: _____ If yes, was original product purchased direct from mfr? <input type="checkbox"/> Yes, <input checked="" type="checkbox"/> No Provide source manufacturer for repackaged product: _____																															
<b>GTIN AND HIBCC PRODUCT INFORMATION</b>				<b>ITEM AND PACKING INFORMATION</b>																															
Saleable Unit of Measure: Item/Each, Box/Carton/Bundle/Inner Pack, Case, Pallet Saleable Quantity: 1, 24		HIBCC: _____ GTIN-14: 00370512038052, 50370512038057 Unit of Use GTIN-14: 370512038052		<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th>Item/Each:</th> <th>Weight Lbs.</th> <th>Dimensions (US msmts.) Depth</th> <th>Width</th> <th>Height</th> <th>Volume (Cube)</th> <th>Saleable # Pieces</th> </tr> </thead> <tbody> <tr> <td>Box/Carton/Bundle/ Inner Pack:</td> <td>0.473994</td> <td>3.26772</td> <td>1.77165</td> <td>5.51181</td> <td>31.90928</td> <td>1</td> </tr> <tr> <td>Case:</td> <td>14.0214</td> <td>14.3701</td> <td>12.0079</td> <td>7.67717</td> <td>1324.7319</td> <td>24</td> </tr> <tr> <td>Pallet:</td> <td>670.249369</td> <td>47.24409</td> <td>39.3701</td> <td>42.51969</td> <td>79086.82</td> <td>1296</td> </tr> </tbody> </table>				Item/Each:	Weight Lbs.	Dimensions (US msmts.) Depth	Width	Height	Volume (Cube)	Saleable # Pieces	Box/Carton/Bundle/ Inner Pack:	0.473994	3.26772	1.77165	5.51181	31.90928	1	Case:	14.0214	14.3701	12.0079	7.67717	1324.7319	24	Pallet:	670.249369	47.24409	39.3701	42.51969	79086.82	1296
Item/Each:	Weight Lbs.	Dimensions (US msmts.) Depth	Width	Height	Volume (Cube)	Saleable # Pieces																													
Box/Carton/Bundle/ Inner Pack:	0.473994	3.26772	1.77165	5.51181	31.90928	1																													
Case:	14.0214	14.3701	12.0079	7.67717	1324.7319	24																													
Pallet:	670.249369	47.24409	39.3701	42.51969	79086.82	1296																													
<b>COST INFORMATION</b> Regular Cost _____ Invoice Cost (WAC) (\$) \$1,168.20 As of date: 8/24/22				<b>WHOLESALE USE ONLY:</b> 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: _____																															



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

Version 2021

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.)  Yes

e. Does the product contain DEHP?  No

Is this product regulated for shipment by DOT?  
 (if yes, answer a-e below and provide SDS)  No

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)  No

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:  No

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#

### SDS Hazard Classification

<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer
<input checked="" type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard

Does the product have an Aerosol class? If yes,  No

Identify NFPA Storage Level:  
 NFPA Storage Level:

Is the product a NIOSH hazardous drug?  
 If yes, indicate which:

### 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:  No

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:



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

Version 2021

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
Purchase orders may be accepted by: a. EDI <input type="checkbox"/> b. Autofax <input type="checkbox"/> c. Fax <input type="checkbox"/> d. Phone only <input type="checkbox"/> e. Supplier Web Site only <input type="checkbox"/> Minimum Order Quantity: <input type="text"/> Supplier's Customer Service Number: <input type="text"/> Contracted 3PL company / contact #: <input type="text"/> Name: <input type="text"/> Phone: <input type="text"/> Fax Number: <input type="text"/> Fax Number: <input type="text"/> Phone No.: <input type="text"/> Site Address: <input type="text"/>	<b>Purchase order daily receipt cut off time by supplier</b> Cut off time: <input type="text"/> Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days Ships same day for next day receipt: <input type="checkbox"/> Ships for second day receipt: <input type="checkbox"/> Ships regular ground for 3-10 days receipt: <input type="checkbox"/>
<b>Expedited Freight Charges or Other Designated Drop Ship Fees:</b> Expedited freight fees billed with each order: <input type="text"/> Drop Ship service fee billed with each order: <input type="text"/> Drop Ship miscellaneous fees billed: <input type="text"/> Comments: <input type="text"/>	<b>Overnight and Priority Overnight PO Processing</b> <b>Overnight receipt available:</b> <input type="checkbox"/> PO Receipt cut off time: <input type="text"/> Days of week overnight is available: <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday <b>Priority Overnight receipt available:</b> <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> <b>Saturday Overnight receipt available:</b> <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="text"/> Overnight Fees apply: <input type="checkbox"/> Other fees apply: <input type="checkbox"/>
<b>Class of Trade Restriction:</b> No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Restricted to retail pharmacy only: <input type="checkbox"/> Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> Restricted from US territories? (explain in comments) <input type="checkbox"/> Comments: <input type="text"/>	<b>Return Instructions</b> Contact # if product is received damaged: <input type="text"/> Is product returnable for credit: <input type="checkbox"/> URL/Link to returns policy: <input type="text"/> Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> If so, which states? Other requirements? Comments? <input type="text"/>
<b>Other Data Information Required to Process PO:</b> Patient Procedure Date: <input type="text"/> Physician Name: <input type="text"/> Physician/Clinic Phone #: <input type="text"/> Physician State License #: <input type="text"/> Physician/Clinic DEA #: <input type="text"/> Physician/Clinic Specialty: <input type="text"/>	<b>ADDITIONAL INFORMATION</b> Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>
<b>Miscellaneous Notes:</b> <input type="text"/>	