

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): 210986 Medical Device Class, if applicable: DUNS: 080121345 Proprietary Name (if Applicable) and Established Name: Diclofenac Sodium Topical Gel, 1% Selling Unit NDC: 70512-0106-10 Unit of Use NDC: 70512-0106-10 UPC: 705120106105 UDI: CVX Code: MVX Code:				a. Temperature – Indicate the USP temperature range for this product. Temperature Range: <input type="text"/> (Controlled Room – between 20 and 25 C (68° – 77° F)) Other Temperature Range Requirement (write in): 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% Topical Gel, 100g Active Ingredient(s): Diclofenac Sodium 1% URL for Additional Product Information: Address: 655 Highlandia Dr. City: Baton Rouge State: LA Address 2: Ste B 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)				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? <input type="checkbox"/> No																															
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION																															
The product is? a legend device? <input type="checkbox"/> No if yes, enter class # 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 <input type="checkbox"/> Unit of Use Is the Product... Orphan Drug Status FDA Approval Status Allergens Present Country of Origin: India		Size: 100g Strength: 1% Dosage Form: Topical gel Product Shape: Product Color: Opaque white gel Product Imprint:		d. Store product (unit of sale) upright? Protect product (unit of sale) from light? e. Shelf life: Initial shelf life at launch (if different):																													
FOR GENERIC DRUG PRODUCTS				ORDER INFORMATION																															
I. Orange Book Rating: II. Generic Equivalent to What Brand?: Voltaren®				Authorized Generic <input type="checkbox"/> *If Authorized Generic, other section fields are not applicable PHARMACY ORDER / BILL UNIT Rec. sell unit to customer? <input type="checkbox"/> 1 tube (Write-in, e.g. 1 Vial) Rx billing unit to pharmacy: <input type="checkbox"/> Each <input type="checkbox"/> Gram <input type="checkbox"/> Milliliter																															
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION				ITEM AND PACKING INFORMATION																															
Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/> Yes Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: OTC exemption 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: 370512000004 GCP: If yes, was original product purchased direct from mfr? Provide source manufacturer for repackaged product																															
GTIN AND HIBCC PRODUCT INFORMATION				<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>0.34</td> <td>2.25</td> <td>1.75</td> <td>7.25</td> <td>28.546875</td> <td>1</td> </tr> <tr> <td>Case</td> <td>8.05</td> <td>14</td> <td>7.75</td> <td>9.5</td> <td>1030.75</td> <td>24</td> </tr> <tr> <td>Pallet</td> <td>644</td> <td>48</td> <td>40</td> <td>46</td> <td>88320</td> <td>1920</td> </tr> </tbody> </table>				Item/Each	Weight Lbs.	Dimensions (US msmts.) Depth	Width	Height	Volume (Cube)	Saleable # Pieces	Box/Carton/Bundle/Inner Pack	0.34	2.25	1.75	7.25	28.546875	1	Case	8.05	14	7.75	9.5	1030.75	24	Pallet	644	48	40	46	88320	1920
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Saleable Unit of Measure Item/Each: <input checked="" type="checkbox"/> X Box/Carton/Bundle/Inner Pack: 1 Case: 24 Pallet:				COST INFORMATION																															
HIBCC: GTIN-14: 00370512106102 / 50370512106107 Unit of Use GTIN-14: 00370512106102				Regular Cost Invoice Cost (WAC) (\$): \$202.31 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:																															



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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) 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

Organic Corrosive
 Inorganic Oxidizer
 Steroid/Androgen 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? No
 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

ADD'L STORAGE INFORMATION

Is the Product...

Controlled Substance? Controlled Substance Code

Controlled by State(s)? Listed Chemical (List I or II)

ARCOS Reportable? 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:

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:



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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
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"/>	Purchase order daily receipt cut off time by supplier 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"/>
Expedited Freight Charges or Other Designated Drop Ship Fees: 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"/>	Overnight and Priority Overnight PO Processing Overnight receipt available: <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 Priority Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Saturday Overnight receipt available: <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"/>
Class of Trade Restriction: 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"/>	Return Instructions 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"/>
Other Data Information Required to Process PO: 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"/> Miscellaneous Notes: <input type="text"/>	ADDITIONAL INFORMATION Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>