

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

Version 2021

Introduction Type: New Item

Final Version

Date: 1/12/2023

PRODUCT INFORMATION		SPECIAL HANDLING AND STORAGE REQUIREMENTS	
Company Name: SOLA Pharmaceuticals 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: SynoFlex Patch Selling Unit NDC: 70512-015-15 Unit of Use NDC: CVX Code: UPC: 370512015152 UDI: MVX Code:		a. Temperature – Indicate the USP temperature range for this product. Temperature Range: (Controlled Room – between 20 and 25 C (68° – 77° F)) 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? <input type="checkbox"/> No Is this product to be shipped to customers on dry ice? <input type="checkbox"/> No	
Description: SynoFlex Patch, Topical pain patch, Lidocaine 4% and Menthol 5%, 15 patches Active Ingredient(s): Lidocaine HCL 4%, Menthol 5% URL for Additional Product Information: Address: 655 Highlandia Dr. City: Baton Rouge State: LA Address 2: Key Contact: Email: info@solameds.us Zip: 70810 Phone Number: 866-747-7365 Fax: 800-754-9550 Product Therapeutic Classification: Topical Anesthetic		b. Contact for temperature excursion questions: Name: 866-747-7365 Number: info@solameds.us Group E-mail:	
ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is? <input type="checkbox"/> No a legend device? <input type="checkbox"/> No if yes, enter class # a product kit? <input type="checkbox"/> No if yes, list NDCs of component parts reverse numbered? 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: USA <input type="checkbox"/> Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> Yes	
FOR GENERIC DRUG PRODUCTS		ORDER INFORMATION	
I. Orange Book Rating: N/A II. Generic Equivalent to What Brand?:		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 box of 15 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	
Authorized Generic <input type="checkbox"/> *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: <input checked="" 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? <input type="checkbox"/> Yes If yes, select exemption: Other exemption - Write in: OTC exemption Is product repackaged? <input type="checkbox"/> No Is product sold by manufacturer's exclusive distributor? <input type="checkbox"/> No Has FDA granted waiver/exception/exemption for product? <input type="checkbox"/> No If yes, attach documentation from FDA.		Weight Lbs., Dimensions (US msmts.) Depth, Width, Height, Volume (Cube), Saleable # Pieces Item/Each: 0, 1 Box/Carton/Bundle/Inner Pack: 0.2, 1, 6.5, 5.75, 37.375, 1 Case: 5.9, 12, 12, 7, 1008, 24 Pallet: 371.7, 36, 36, 49, 63504, 1512	
GTIN AND HIBCC PRODUCT INFORMATION		COST INFORMATION	
Saleable Unit of Measure, Saleable Quantity, HIBCC, GTIN-14, Unit of Use GTIN-14 Item/Each: 1 Box/Carton/Bundle/Inner Pack: 24 Case: 1512 00370512015152 50370512015157 70370512015151		Regular Cost Invoice Cost (WAC) (\$): \$859.95 As of date: 5/12/22	
*Please provide any additional information on page 2.		WHOLESALE USE ONLY: Vendor #: Whst. Code #: Finline Code:	
Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.		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

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"/>	ADDITIONAL INFORMATION Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>
Miscellaneous Notes: <input type="text"/>	