

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

Version 2024						Introduction Type:	New Item		Final Version			Date:	4/29/	2023
			PRODUCT INFORMAT	TION					SPECIAL HAN	DLING AND STOR	AGE REQUIF	REMENTS*		
Company Name: SOLA Pharmaceuticals Application: ANDA								a. Temperature – Indicate the USP temperature range for this product.						
Application Number for NDA/ANI						NDA 505(b) Type:				Controlled Room -		and 25 C (68	– 77° F)	
Medical Device Class, if applicab	ole:]						
DUNS:	080121345								Other Temperature Range F	Requirement				
Proprietary Name (If Applicable) a		ame: Baclofer	n Tablets USP 10mg						(write in)					
Selling Unit NDC:	70512-782-10		Unit of Use NDC:				12782108		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Baclofen Tablets	USP 10mg 100ct						1	Is this product to be shipped	to customers on id	ce?		No	
									Is this product to be shipped	d to customers on d	Iry ice?		No	
Active Ingredient(s): Baclofen														
								b. Contact for temperature excursion questions:						
URL for Additional Product Inform Address:	ation: 655 Highlandia D	_				Address 2:		-	Name:		866-747-736	-		
City:	Baton Rouge	i.			State:		70810	-	Number: Group E-mail:					
Key Contact:	Daton Rouge					info@solameds.us	70010	Group E-mail: <u>info@solameds.us</u>						
Phone Number:	866-747-7365				Fax:	800-754-9550		c. Special regulations for product in any states?						
Product Therapeutic Classification		Muscle Relaxant/Anti	spastic Agent					1	Special returns requirements				No	
	ADDITI	ONAL PRODUCT INFO	ORMATION			PRODUCT DESCR	RIPTION INFORMATION	d. Store prod	uct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship O	nlv			il '	Protect product (unit of sa	le) from light?			No	
a legend device?		No	Is the Product	Neither	,		100ct	e. Shelf life:	r rotoot product (unit or ou	,			24	Months
if yes, enter class #		1.12	Orphan Drug Status			Size:			Initial shelf life at launch (i	if different):				Months
a product kit?		No				Strength:	10mg		•	•				
if yes, list NDCs of			FDA Approval Status			ou engui.				ORDER INFORM	IATION			
component parts						Dosage Form:	Tablet; Oral							
reverse numbered?		No				_			Unit of Sale		What is the	NDC selling	unit?	
co-licensed? latex-free?		No Yes	Allergens Present				Round		X Bottle Box/Carton		1 Bottle	g. 1 Box of 10	\/iolo\	
preservative-free?		No				Product Shape:	rtourid		Ampule		(**************************************	g. 1 DOX 01 10	viais)	
correctional institution block?		No					White		Glass		Minimum or	der quantity	?	Yes
opioid?		No				Product Color:			Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint:	24		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for					Product imprint.			Vial Liquid Multi		If Yes, how		ch package t	ype?
hospital scanning?			Is this product covered up	nder the					Vial Powder Sql		24	Each		
'								11						
If Unit Dose, indicate NDC here:			Trade Agreements Act (T		No				Vial Power Multi			Inner/Carton	Pack	
If Unit Dose, indicate NDC here:			Trade Agreements Act (T	ГАА)?	No							Inner/Carton Case	Pack	
If Unit Dose, indicate NDC here:				ГАА)?	No				Vial Power Multi				Pack	
If Unit Dose, indicate NDC here:			Trade Agreements Act (T	ГАА)?		thorized Generic *If Au	uthorized Generic other		Vial Power Multi Other: Write In	ARMACY ORDER	1		Pack	
	AD		Trade Agreements Act (T	ГАА)?			uthorized Generic, other	Peo cell unit	Vial Power Multi Other: Write In	ARMACY ORDER	1 / BILL UNIT	Case		
I. Orange Book Rating:	AB		Trade Agreements Act (T	ГАА)?			uthorized Generic, other on fields are not applicable		Vial Power Multi Other: Write In	ARMACY ORDER	1 / BILL UNIT Rx billing ur	Case		
		Lioresal	Trade Agreements Act (T	ГАА)?				1	Vial Power Multi Other: Write In PH to customer? Bottle of 100Ct	ARMACY ORDER	1 / BILL UNIT	Case nit to pharma Each		
I. Orange Book Rating:		Lioresal	Trade Agreements Act (T	ODUCTS	Au				Vial Power Multi Other: Write In PH to customer? Bottle of 100Ct 1 Vial)	ARMACY ORDER	1 / BILL UNIT Rx billing ur	Case		
I. Orange Book Rating: II. Generic Equivalent to What Brad	nd?:	Lioresal DRUG SUPPLY	Trade Agreements Act (T FOR GENERIC DRUG PRO	ODUCTS	Au	section		(Write-in, e.g.	Vial Power Multi Other: Write In PH to customer? Bottle of 100Ct 1 Vial) de:]	/ BILL UNIT Rx billing ur	Case nit to pharma Each Gram Milliliter		
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I. Orange Book Rating: II. Generic Equivalent to What Brai Does supplier meet DSCSA definit Is product exempt from DSCSA? If yes, select exemption:	nd?:	Lioresal DRUG SUPPLY	Trade Agreements Act (T FOR GENERIC DRUG PRO CHAIN SECURITY ACT (Yes	ODUCTS	Au	section		(Write-in, e.g.	Vial Power Multi Other: Write In PH to customer? Bottle of 100Ct 1 Vial) Je: ITEM	AND PACKING IN	/ BILL UNIT Rx billing un 1 NFORMATION ons (US msm	Case nit to pharma Each Gram Milliliter	cy:	Saleable #
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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): SDS Hazard Classification No a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? No x Organic Corrosive Is the product a CA Prop 65 reproductive toxicant? Inorganic Oxidizer No Does the product label bear a CA Prop 65 warning? Steroid/Androgen No Contact Hazard c. Contact Hazard? Does the product have an Aerosol class? If yes, No No identify NFPA Storage Level: d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) NFPA Storage Level: e. Does the product contain DEHP? No Is this product regulated for shipment by DOT? No Is the product a NIOSH hazardous drug? No (if yes, answer a-e below and provide SDS) If yes, indicate which: a. UN/Identification Number b. Proper Shipping Name Hazardous Waste Identification c. DOT Hazard Class d. Packing Group EPA Hazardous Waste Code: Waste Characteristics e. Inhalation Hazard? No Is this product regulated for shipment by IATA? No (if yes, answer a-e below and provide SDS) **REMS or REGISTRY RESTRICTIONS** a. UN/Identification Number b. Proper Shipping Name Is there a REMS on this product? c. DOT Hazard Class If Yes, is it managed with a pharmacy registry? No d. Packing Group Website URL: e. Inhalation Hazard? No Is the product restricted for air shipment? If so, indicate restriction: Med Guide Required No No Passenger Limited Distribution Requirement No Comments / Details: (For example, iPledge program?) Cargo Passenger & Cargo Is this a reportable quantity? REMS: No Phone: RQ Threshold: REMS Program Manager Name: Is this a marine pollutant? Supplier Manages REMS registry exclusively: Wholesale distributor support: Is this product shipped utilizing an authorized DOT exception or Special Permit? Provider Name: (if yes, identify method below) DEA #: Limited Quantity Site Enrollment Number assigned NCPDP# Consumer Commodity, ORM-D by Supplier: NPI#: Small Quantity (49 CFR 173.4) Special Permit: DOT-SP Comments Special Provision (listed in Column 7 of 49 CFR 172.101); SP# Registry: Phone: Registry Program Contact Name: ADD'L STORAGE INFORMATION Comments Is the Product... RETURN INSTRUCTIONS Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) No 866-747-7365 ARCOS Reportable? No If yes, indicate which: Contact tel. # if product received damaged: Schedule No. Is it a scheduled listed chemical product?: Yes Is product returnable for credit: **CLASS OF TRADE RESTRICTION:** URL/Link to returns policy: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes Restricted to retail pharmacy only: No Special regulations or returns requirements for this product in certain states? Restricted to hospital, clinics, and physician offices only: No No Restricted from US territories? (explain in comments) If so, which states? Other requirements? Comments? No Comments: MISCELLANEOUS NOTES and/or Image of Product Barcode



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

Version 2024

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:		Purchase order daily receipt cut off time by supplier
a. EDI		Cut off time:
b. Autofax	Fax Number:	
c. Fax	Fax Number:	Shipping lead time of PO: Hours Days
d. Phone only	Phone No.:	
e. Supplier Web Site only	Site Address:	Ships same day for next day receipt:
Minimum Order Quantity:		Ships for second day receipt:
Supplier's Customer Service Number:	N	Ships regular ground for 3-10 days receipt:
Contracted 3PL company / contact #:	Name:	
	Phone:	
Expedited Freight Cha	rges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each orde	er:	Overnight receipt available:
Drop Ship service fee billed with each orde	r:	PO Receipt cut off time:
Drop Ship miscellaneous fees billed:		Days of week overnight is available: Monday
Comments:		Tuesday
		Wednesday
		Thursday
		Friday
		Priority Overnight receipt available:
Cla	ss of Trade Restriction:	PO Receipt Cut off time:
No restriction: Soloct VES if sold to retail al	narmacy, hospitals, clinics and physician offices	Saturday Overnight receipt available:
Restricted to retail pharmacy only:	lamacy, nospitals, clinics and physician onices	PO Receipt Cut off time:
Restricted to hospital, clinics, and physiciar	n offices only:	Phone:
Restricted from US territories? (explain in c		Order receipt method: Fax: Fax #:
Comments:		EDI:
		Overnight Fees apply:
		Other fees apply:
Other Data Inf	ormation Required to Process PO:	Return Instructions
Patient Procedure Date:		Contact # if product is received damaged:
Physician Name:		Is product returnable for credit:
Physician/Clinic Phone #		URL/Link to returns policy:
Physician State License #		Grazania to rotatno ponoj.
Physician/Clinic DEA #:		Special regulations or returns requirements for this product in certain states?
Physician/Clinic Specialty:		If so, which states? Other requirements? Comments?
	Miscellaneous Notes:	
		ADDITIONAL INFORMATION
		Is product order for scheduled patient procedure?
		Is product order for restocking purposes?