

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

Company Name: Oliva Therapeutics, LLC Application: ANDA	n light.			
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): Temperature Range	n light.			
DUNS: 118637856	n light.			
Proprietary Name (If Applicable) and Established Name: Digoxin Tablets, USP 125mcg (0.125mg) Selling Unit NDC: Selling Unit NDC: Unit of Use NDC: UPC: Selling Unit NDC: USes Selling Unit NDC:	n light.			
Selling Unit NDC: UDI Bases-201-10 UDI CVX Code: Digoxin Tablets, USP, 125 mcg (0.125 mg), Scored I.D. Imprint JSP-544 (yellow). Active Ingredient(s): URL for Additional Product Information: Address: Address: Address: Af N Broad St, Ste 504 Key Contact: Phone Number: Address: Addres				
UDI CVX Code: MVX Code: Digoxin Tablets, USP, 125 mcg (0.125 mg), Scored I.D. Imprint JSP-544 (yellow). Active Ingredient(s): URL for Additional Product Information: Address: 45 N Broad St, Ste 504 City: Ridgewood Fax: Digoxin Address 2: State: Email: Fax: Digoxin Address 2: State: Email: Fax: Digoxin Address 2: State: Email: Co. Special regulations for product in any states? Co. Special regulations for product in any states? No defined in the USP. No No No No No No No No No N	ner as			
Description: Digoxin Tablets, USP, 125 mcg (0.125 mg), Scored I.D. Imprint JSP-544 (yellow). Active Ingredient(s): Digoxin URL for Additional Product Information: Address: 45 N Broad St, Ste 504 City: Ridgewood Rey Contact: Phone Number: Contact: Phone Number: Digoxin Is this product to be shipped to customers on ice? No Is this product to be shipped to customers on ice? Is this product to be shipped to customers on ice? Is this product to be shipped to customers on ice? Is this product to be shipped to customers on ice? Is this product to be shipped to customers on ice? Is this product to be shipped to customers on ice? Is this product to be shipped to customers on ice? Is the is the product to be shipped to customers on ice? Is the is the product to be shipped to customers on ice? Is the is the product in the pro				
Sthis product to be shipped to customers on dry ice? No				
Active Ingredient(s): URL for Additional Product Information: Address: 45 N Broad St, Ste 504 City: Ridgewood Key Contact: Phone Number: 201-735-8618 Digoxin b. Contact for temperature excursion questions: Name: Number: 877-200-6088 option 1 Group E-mail: C. Special regulations for product in any states? No				
URL for Additional Product Information:				
Address: 45 N Broad St, Ste 504 Address 2: Number: 877-200-6088 option 1 City: Ridgewood State: NJ Zip: 07450 Email: Fax: 201-735-8618 Number: 677-200-6088 option 1 Concept Support State: NJ Signary State: Support State: Suppor				
City: Ridgewood State: NJ Zip: 07450 Group E-mail: Key Contact: Email: Fax: 201-735-8614 C. Special regulations for product in any states? No				
Key Contact: Email: Phone Number: 201-735-8618 Fax: 201-735-8614 c. Special regulations for product in any states? No				
Product Therapeutic Classification: Antiarrhythmics Special returns requirements for this product? No				
ADDITIONAL PRODUCT INFORMATION PRODUCT DESCRIPTION INFORMATION d. Store product (unit of sale) upright?				
a logged device?	Months			
a regend device: Size: 1000	Months			
a product kit? No Strength: 125mcg (0.125mg)				
if yes, list NDCs of FDA Approval Status ORDER INFORMATION				
component parts Dosage Form: Tablets Unit of Sale What is the NDC selling unit?				
co-licensed? No Allergens Present x Bottle 1 Bottle of 1000 Tablets				
latex-free? Yes Product Shape: Round Box/Carton (Write-in, e.g. 1 Box of 10 Vials)				
preservative-free? Yes	.,			
correctional institution block? opioid? No Product Color: Vellow Glass Minimum order quantity? Tube	Yes			
Connehinoid? No. Country of Origin UICA Sported ID Imprint ISB				
If Unit Dose, is item bar coded to unit dose for hospital Vial Liquid Multi If Yes, how many of which package ty	pe?			
scanning? Is this product covered under the Vial Powder Sql 24 Each				
If Unit Dose, indicate NDC here: Trade Agreements Act (TAA)? Yes Vial Power Multi Inner/Carton/Pack Other: Write In Case				
FOR GENERIC DRUG PRODUCTS				
Authorized Generic *If Authorized Generic, other section PHARMACY ORDER / BILL UNIT				
I. Orange Book Rating: AB fields are not applicable Rec. sell unit to customer? Rx billing unit to pharmacy:				
II. Generic Equivalent to What Brand?:				
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION (Write-in, e.g. 1 Vial) Gram Milliliter				
Does supplier meet DSCSA definition of manufacturer? Is product exempt from DSCSA? No ITEM AND PACKING INFORMATION				
If yes, select exemption: Other exemption - Write in: Dimensions (US msmts.) Volume Other exemption - Write in: Depth Width Height (Cube)	# Pieces:			
le product range/grand?	4			
Is product reparkaged? Is product sold by manufacturer's exclusive distributor? No direct from mfr?	1			
Has FDA granted waiver/exception/exemption for product? No If yes, attach documentation from FDA. Box/Carton/Bundle/ Inner Pack:				
CTIN AND HIRCC PRODUCT INFORMATION				
5.05 lbs 11.75" 8" 4.63"	24			
Saleable Unit of Measure Quantity HIBCC GTIN-14 Unit of Use GTIN-14 Pallet: 1353 lbs 48" 39.5" 65.13"	260			
X tem/Each 1 00382685201102				
	:			
Palet				
Regular Cost Vendor #:				
Invoice Cost (WAC) (\$) \$236.70 Whsl. Code #: Fineline Code:				
As of date: 6/27/2023				
Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.				



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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? No	SDS Hazard Classification Organic Corrosive
Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning? No	x Inorganic Oxidizer Steroid/Androgen Contact Hazard
c. Contact Hazard? d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) e. Does the product contain DEHP? No	Aerosol Class; Identify NFPA Storage Level: Is the product a NIOSH hazardous drug? If yes, indicate which:
Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics
d. Packing Group e. Inhalation Hazard? No	
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class	REMS or REGISTRY RESTRICTIONS Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:
d. Packing Group e. Inhalation Hazard? Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)
Passenger & Cargo	REMS: REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier: No Phone: DEA #: PCPDP#: NPI #:
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments Registry: No
ADD'L STORAGE INFORMATION	Registry Program Contact Name: Phone: Comments
Is the Product Controlled Substance? Controlled Substance Code Controlled by State(s)? ARCOS Reportable? Schedule No. No Controlled Substance Code Listed Chemical (List I or II) No If yes, indicate which: Is it a scheduled listed chemical product?:	RETURN INSTRUCTIONS Contact tel. # if product received damaged: Is product returnable for credit:
CLASS OF TRADE RESTRICTION: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	URL/Link to returns policy:
Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)	Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?
Comments:	
MISCELLANEC	OUS NOTES and/or Image of Product Barcode:



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Version 2020

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 Number:	Shipping lead time of PO: Hours Days
d. Phone only	
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:	Ships regular ground for 3-10 days receipt:
Contracted 3PL company / contact #: Name:	
Phone:	
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:	Overnight receipt available:
Drop Ship service fee billed with each order:	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:
Class of Trade Restriction:	
	PO Receipt Cut off time:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Saturday Overnight receipt available:
Restricted to retail pharmacy only:	PO Receipt Cut off time:
Restricted to hospital, clinics, and physician offices only:	Order receipt method: Phone: Phone #:
Restricted from US territories? (explain in comments)	Fax: Fax #:
Comments:	EDI:
	Overnight Fees apply:
	Other fees apply:
Other Data Information 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 #	
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?