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

Version 2020 | Introduction Type: | Final Version | Date: 6/27/23

PRODUCT INFORMATION

Company Name: Oliva Therapeutics, LLC | Application: ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 76-268
DUNS: 118637856
Proprietary Name (If Applicable) and Established Name: Digoxin Tablets, USP 250mcg (0.25mg)
Selling Unit NDC: 82685-202-10 | Unit of Use NDC: | UPC: 3-8268520210-9
UDI: | CVX Code: | MVX Code:
Description: Digoxin Tablets, USP, 250 mcg (0.250 mg), Scored I.D. Imprint JSP-545 (white).
Active Ingredient(s): Digoxin
URL for Additional Product Information:
Address: 45 N Broad St, Ste 504 | Address 2:
City: Ridgewood | State: NJ | Zip: 07450
Key Contact: | Email:
Phone Number: 201-735-8618 | Fax: 201-735-8614
Product Therapeutic Classification: Antiarrhythmics

ADDITIONAL PRODUCT INFORMATION

The product is?
- a legend device? No
- if yes, enter class #
- a product kit? No
- if yes, list NDCs of component parts
- reverse numbered? No
- co-licensed? No
- latex-free? Yes
- preservative-free? Yes
- correctional institution block? No
- opioid? No
- Cannabinoid? No

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
Is the Product…
Orphan Drug Status
FDA Approval Status
Allergens Present
Country of Origin: USA
Is this product covered under the Trade Agreements Act (TAA)? Yes

PRODUCT DESCRIPTION INFORMATION

Size:	1000
Strength:	250mcg (0.25mg)
Dosage Form:	Tablets
Product Shape:	Round
Product Color:	White
Product Imprint:	Scored I.D. Imprint JSP-545

FOR GENERIC DRUG PRODUCTS

Authorized Generic | *If Authorized Generic, other section fields are not applicable

I. Orange Book Rating: AB
II. Generic Equivalent to What Brand?: Lanoxin®

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? Yes
Is product exempt from DSCSA? No
If yes, select exemption:
Other exemption - Write in:
Is product repackaged? No
Is product sold by manufacturer's exclusive distributor? No
Has FDA granted waiver/exception/exemption for product? No
GLN:
If Yes, was original product purchased direct from mfr?
If yes, attach documentation from FDA.

GTIN AND HIBCC PRODUCT INFORMATION

	Saleable Unit of Measure	Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
x	Item/Each	1		00382685202109	
	Box/Carton/Bundle/Inner Pack				
x	Case	24		50382685202104	
	Pallet				

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.
Temperature Range
Other Temperature Range Requirement (write in): Store at controlled room temperature 15°-25°C (59°-77°F) in a dry place and protect from light.
Notes: Dispense in a tight, light-resistant container as defined in the USP.
Is this product to be shipped to customers on ice? No
Is this product to be shipped to customers on dry ice? No

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
Special returns requirements for this product? No

d. Store product (unit of sale) upright? No
Protect product (unit of sale) from light? Yes

e. Shelf life: 24 Months
Initial shelf life at launch (if different): Months

ORDER INFORMATION

Unit of Sale:
- x Bottle
- Box/Carton
- Ampule
- Glass
- Tube
- Vial Liquid Sgl
- Vial Liquid Multi
- Vial Powder Sql
- Vial Power Multi
- Other: Write In

What is the NDC selling unit? 1 Bottle of 1000 Tablets
(Write-in, e.g. 1 Box of 10 Vials)
Minimum order quantity? Yes
If Yes, how many of which package type?
24 Each
Inner/Carton/Pack
Case

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?
(Write-in, e.g. 1 Vial)
Rx billing unit to pharmacy:
- Each
- Gram
- Milliliter

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.) Depth	Width	Height	Volume (Cube)	# Pieces:
Item/Each:	158.76gm	2.13"	2.13"	4.75"		1
Box/Carton/Bundle/ Inner Pack:						
Case:	9.55 lbs	13.5"	9.31"	5.75"		24
Pallet:	1281.50 lbs	46.56"	36.31"	62.5"		130

COST INFORMATION

Regular Cost
Invoice Cost (WAC) ($): $236.70
As of date: 6/27/2023

WHOLESALER USE ONLY:

Vendor #:
Whsl. Code #:
Fineline Code:

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

*Please provide any additional information on page 2. 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? No

(If yes, attach SDS with special instructions.)

e. Does the product contain DEHP? No

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

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

d. Packing Group

e. Inhalation Hazard? No

Is the product restricted for air shipment? If so, indicate restriction:

- [ ] 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
- [x] Inorganic
- [ ] Steroid/Androgen
- [ ] Corrosive
- [ ] Oxidizer
- [ ] Contact Hazard

[ ] Aerosol Class; Identify 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?

Website URL:

Med Guide Required

Limited Distribution Requirement

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: PCPDP#:

NPI #:

Comments

Registry: No

Registry Program Contact Name: Phone:

Comments

ADD'L STORAGE INFORMATION

Is the Product…

Controlled Substance? No

Controlled by State(s)? No

ARCOS Reportable? No

Schedule No.

Controlled Substance Code

Listed Chemical (List I or II) No

If yes, indicate which:

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

Restricted to retail pharmacy only:

Restricted to hospital, clinics, and physician offices only:

Restricted from US territories? (explain in comments)

Comments:

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 877-200-6088 option 2

Is product returnable for credit:

URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states?

If so, which states? Other requirements? Comments?

MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE

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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

Purchase orders may be accepted by:

a. EDI
b. Autofax — Fax Number:
c. Fax — Fax Number:
d. Phone only — Phone No.:
e. Supplier Web Site only — Site Address:

Minimum Order Quantity:
Supplier's Customer Service Number:
Contracted 3PL company / contact #: Name:
Phone:

Standard Order Receipt and Processing

Purchase order daily receipt cut off time by supplier
Cut off time:

Shipping lead time of PO: Hours Days

Ships same day for next day receipt:
Ships for second day receipt:
Ships regular ground for 3-10 days receipt:

Expedited Freight Charges or Other Designated Drop Ship Fees:

Expedited freight fees billed with each order:
Drop Ship service fee billed with each order:
Drop Ship miscellaneous fees billed:
Comments:

Overnight and Priority Overnight PO Processing

Overnight receipt available:
PO Receipt cut off time:
Days of week overnight is available:
- Monday
- Tuesday
- Wednesday
- Thursday
- Friday

Priority Overnight receipt available:
PO Receipt Cut off time:

Saturday Overnight receipt available:
PO Receipt Cut off time:

Order receipt method:
Phone: Phone #:
Fax: Fax #:
EDI:

Overnight Fees apply:
Other fees apply:

Class of Trade Restriction:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices
Restricted to retail pharmacy only:
Restricted to hospital, clinics, and physician offices only:
Restricted from US territories? (explain in comments)
Comments:

Other Data Information Required to Process PO:

Patient Procedure Date:
Physician Name:
Physician/Clinic Phone #
Physician State License #
Physician/Clinic DEA #:
Physician/Clinic Specialty:

Return Instructions

Contact # if product is received damaged:
Is product returnable for credit:
URL/Link to returns policy:
Special regulations or returns requirements for this product in certain states?
If so, which states? Other requirements? Comments?

Miscellaneous Notes:

ADDITIONAL INFORMATION

Is product order for scheduled patient procedure?
Is product order for restocking purposes?