



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

Version 2021 Introduction Type: New Item Final Version Date:

PRODUCT INFORMATION **SPECIAL HANDLING AND STORAGE REQUIREMENTS***

Company Name: Eugia US LLC (f/k/a AuroMedics Pharma LLC) **Application:** ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 203385
Medical Device Class, if applicable: _____
DUNS: 968961354
Proprietary Name (If Applicable) and Established Name: Dactinomycin for Injection (Lyo) 0.5mg - 1s
Selling Unit NDC: 55150-431-01 **Unit of Use NDC:** 55150-431-01 **UPC:** 355150431014
UDI: NA **CVX Code:** _____ **MVX Code:** _____
Description: Dactinomycin for Injection (Lyo) 0.5mg
Active Ingredient(s): Dactinomycin USP 500 mcg
URL for Additional Product Information: eugiaus.com
Address: 279 Princeton-Hightstown Road **Address 2:** _____
City: East Windsor **State:** NJ **Zip:** 08520
Key Contact: _____ **Email:** _____
Phone Number: 888-238-7880 **Fax:** 732-355-9449
Product Therapeutic Classification: Anti -Cancer

a. Temperature – Indicate the USP temperature range for this product.
 Temperature Range:
 Other Temperature Range Requirement:
 Notes: _____
 Is this product to be shipped to customers on ice?
 Is this product to be shipped to customers on dry ice?
b. Contact for temperature excursion questions:
Name: Kevin Cagnetti
Number: 732.839.9400 ex 8009
Group E-mail: kcagnetti@EugiaUS.com
c. Special regulations for product in any states?
 Special returns requirements for this product?
d. Store product (unit of sale) upright?
e. Shelf life: Months
 Protect product (unit of sale) from light?
 Initial shelf life at launch (if different): _____ Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device? if yes, enter class #	<input type="text" value="No"/>	Is the Product... Direct-Ship Only	<input type="text" value="Neither"/>
a product kit? if yes, list NDCs of component parts reverse numbered?	<input type="text" value="No"/>	Is the Product... Orphan Drug Status	<input type="text" value=""/>
co-licensed?	<input type="text" value="No"/>	FDA Approval Status	<input type="text" value=""/>
latex-free?	<input type="text" value="No"/>	Allergens Present	<input type="text" value="No"/>
preservative-free?	<input type="text" value="Yes"/>	Country of Origin	<input type="text" value="India"/>
correctional institution block? opioid? Cannabinoid?	<input type="text" value="No"/>	Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="No"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text" value=""/>		
If Unit Dose, indicate NDC here:	<input type="text" value=""/>		
		Size:	<input type="text" value="2mL 13 mm"/>
		Strength:	<input type="text" value="500Mcg"/>
		Dosage Form:	<input type="text" value="lyophilized powder"/>
		Product Shape:	<input type="text" value="Amber Tubular"/>
		Product Color:	<input type="text" value="Yellow to orange"/>
		Product Imprint:	<input type="text" value="NA"/>

ORDER INFORMATION

Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	<input type="text" value="55150-431-01"/>
<input type="checkbox"/> X Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	Minimum order quantity? <input type="text" value="Yes"/>
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	If Yes, how many of which package type?
<input type="checkbox"/> Vial Powder Sgl	<input type="text" value="1"/> Each
<input type="checkbox"/> Vial Power Multi	<input type="text" value="1"/> Inner/ Carton/Pack
<input type="checkbox"/> Other: Write In	<input type="text" value="1"/> Case

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: Authorized Generic *If Authorized Generic, other section fields are not applicable
II. Generic Equivalent to What Brand?:

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?	Rx billing unit to pharmacy:
<input type="text" value="1 vial"/>	<input checked="" type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Gram
	<input type="checkbox"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?
Is product exempt from DSCSA?
GLN: _____
If yes, select exemption: _____
Other exemption - Write in: _____
GCP: _____
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. _____
If yes, was original product purchased direct from mfr?

ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.22	1.5748	1.5748	3.26772	8.1039294	1
Box/ Carton/ Bundle/ Inner Pack:						
Case:	10.59	10.8268	7.67717	7.87402	654.48212	48
Pallet:	63.36	48.0315	40	40.70866	78211.92	2304

GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1		00355150431014	00355150431014
Box/ Carton/ Bundle/ Inner Pack				
Case	48		50355150431019	
Pallet	2304		70355150431013	

COST INFORMATION **WHOLESALE USE ONLY:**

Regular Cost _____
Invoice Cost (WAC) (\$)
As of date:
Vendor #: _____
Whsl. Code #: _____
Fine Line Code: _____

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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION							
<p>Is this product (check all that apply):</p> <p>a. Cytotoxic? <input type="checkbox"/> Yes</p> <p>b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? <input type="checkbox"/> No Is the product a CA Prop 65 reproductive toxicant? <input type="checkbox"/> No Does the product label bear a CA Prop 65 warning? <input type="checkbox"/> No</p> <p>c. Contact Hazard? <input type="checkbox"/> Yes</p> <p>d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) <input type="checkbox"/> Yes</p> <p>e. Does the product contain DEHP? <input type="checkbox"/> No</p> <p>Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) <input type="checkbox"/> Yes</p> <p>a. UN/Identification Number <input type="text" value="UN 3249"/></p> <p>b. Proper Shipping Name <input type="text" value="Medicine, solid, toxic, n.o.s. (Dactinomycin)"/></p> <p>c. DOT Hazard Class <input type="text" value="Hazard Class: 6.1"/></p> <p>d. Packing Group <input type="text" value="III"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/> Yes</p> <p>Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS) <input type="checkbox"/> Yes</p> <p>a. UN/Identification Number <input type="text" value="UN 3249"/></p> <p>b. Proper Shipping Name <input type="text" value="Medicine, solid, toxic, n.o.s. (Dactinomycin)"/></p> <p>c. DOT Hazard Class <input type="text" value="Hazard Class: 6.1"/></p> <p>d. Packing Group <input type="text" value="III"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/> No</p> <p>Is the product restricted for air shipment? If so, indicate restriction: <input type="checkbox"/> No</p> <p><input type="checkbox"/> Passenger <input type="checkbox"/> Cargo <input type="checkbox"/> Passenger & Cargo</p> <p>Is this a reportable quantity? <input type="checkbox"/> No RQ Threshold: <input type="text"/></p> <p>Is this a marine pollutant? <input type="checkbox"/> Yes</p> <p>Is this product shipped utilizing an authorized DOT exception or Special Permit? <input type="checkbox"/> Yes (if yes, identify method below) <input type="checkbox"/> Limited Quantity <input type="checkbox"/> Consumer Commodity, ORM-D <input checked="" type="checkbox"/> Small Quantity (49 CFR 173.4) <input type="checkbox"/> Special Permit; DOT-SP <input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101); SP# <input type="text"/></p>	<div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p style="text-align: center; margin: 0;">SDS Hazard Classification</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;"><input type="checkbox"/> Organic</td> <td style="width: 50%; border: none;"><input type="checkbox"/> Corrosive</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Inorganic</td> <td style="border: none;"><input type="checkbox"/> Oxidizer</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Steroid/Androgen</td> <td style="border: none;"><input checked="" type="checkbox"/> Contact Hazard</td> </tr> </table> <p>Does the product have an Aerosol class? If yes, identify NFPA Storage Level: <input type="text" value="No"/></p> <p>NFPA Storage Level: <input type="text"/></p> <p>Is the product a NIOSH hazardous drug? If yes, indicate which: <input type="text"/></p> </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p style="text-align: center; margin: 0;">Hazardous Waste Identification</p> <p>EPA Hazardous Waste Code: <input type="text"/> Waste Characteristics: <input type="text"/></p> </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p style="text-align: center; margin: 0;">REMS or REGISTRY RESTRICTIONS</p> <p>Is there a REMS on this product? <input type="checkbox"/> No</p> <p>If Yes, is it managed with a pharmacy registry? Website URL: <input type="text"/></p> <p>Med Guide Required <input type="checkbox"/> No</p> <p>Limited Distribution Requirement <input type="checkbox"/> No</p> <p>Comments / Details: (For example, iPledge program?) <input type="text"/></p> <p>REMS: <input type="checkbox"/> No</p> <p>REMS Program Manager Name: <input type="text"/> Phone: <input type="text"/></p> <p>Supplier Manages REMS registry exclusively: <input type="text"/></p> <p>Wholesale distributor support: <input type="text"/></p> <p>Provider Name: <input type="text"/> DEA #: <input type="text"/></p> <p>Site Enrollment Number assigned by Supplier: <input type="text"/> NCPDP#: <input type="text"/></p> <p>NPI #: <input type="text"/></p> <p>Comments: <input type="text"/></p> <p>Registry: <input type="checkbox"/> No</p> <p>Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/></p> <p>Comments: <input type="text"/></p> </div>	<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive	<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer	<input type="checkbox"/> Steroid/Androgen	<input checked="" type="checkbox"/> Contact Hazard
<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive						
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer						
<input type="checkbox"/> Steroid/Androgen	<input checked="" type="checkbox"/> Contact Hazard						
ADD'L STORAGE INFORMATION							
<p>Is the Product...</p> <p>Controlled Substance? <input type="checkbox"/> No</p> <p>Controlled by State(s)? <input type="checkbox"/> No</p> <p>ARCOS Reportable? <input type="checkbox"/> No</p> <p>Schedule No. <input type="text"/></p> <p>Controlled Substance Code <input type="text"/></p> <p>Listed Chemical (List I or II) <input type="checkbox"/> No</p> <p>If yes, indicate which: <input type="text"/></p> <p>Is it a scheduled listed chemical product?: <input type="checkbox"/> No</p>							
CLASS OF TRADE RESTRICTION:							
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Yes</p> <p>Restricted to retail pharmacy only: <input type="checkbox"/> No</p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> No</p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/> No</p> <p>Comments: <input type="text"/></p>							
RETURN INSTRUCTIONS							
<p>Contact tel. # if product received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/> Yes</p> <p>URL/Link to returns policy: <input type="text" value="https://eugiaus.com/policies/return-policy/"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="text"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>							
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:	Overnight and Priority Overnight PO Processing
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 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"/>	
Other Data Information Required to Process PO:	Return Instructions
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"/>	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"/>
Miscellaneous Notes:	
	ADDITIONAL INFORMATION Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>