



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

Version 2021

Introduction Type:  New Item

Final Version

Date: 10/24/2022

PRODUCT INFORMATION	
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):	213717
Medical Device Class, if applicable:	
DUNS:	968961354
Proprietary Name (If Applicable) and Established Name:	
Selling Unit NDC:	55150-359-50
Unit of Use NDC:	55150-359-01
UPC:	355150359011
UDI	
CVX Code:	
MX Code:	
Description:	Doxercalciferol Injection, 4 mcg/2 mL (2 mcg/mL)(MDV) [50's]
Active Ingredient(s):	Doxercalciferol
URL for Additional Product Information:	eugiaus.com
Address:	279 Princeton-Hightstown Road
City:	East Windsor
State:	NJ
Address 2:	
Zip:	08520
Key Contact:	
Phone Number:	888-238-7880
Fax:	732-355-9449
Product Therapeutic Classification:	

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
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)	Store at 25°C (77°F). Excursions permitted to 15°C to 30°C (59°F to 86°F)
Notes	
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"/>
b. Contact for temperature excursion questions:	
Name:	Kevin Cagnetti
Number:	732-839-9400 x8009
Group E-mail:	kcagnetti@EugiaUS.com
c. Special regulations for product in any states?	<input type="checkbox"/> No
Special returns requirements for this product?	<input type="checkbox"/> No
d. Store product (unit of sale) upright?	<input type="checkbox"/> No
Protect product (unit of sale) from light?	<input type="checkbox"/> No
e. Shelf life:	24 Months
Initial shelf life at launch (if different):	<input type="checkbox"/> Months

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

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input type="checkbox"/> Bottle	55150-359-50
<input checked="" type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	Minimum order quantity?
<input type="checkbox"/> Tube	<input type="checkbox"/> Yes
<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="checkbox"/> Each
<input type="checkbox"/> Vial Power Multi	<input type="checkbox"/> Inner/ Carton/Pack
<input type="checkbox"/> Other: Write In	<input type="checkbox"/> 1 Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AP
II. Generic Equivalent to What Brand?:	Hectorol Injection
<input type="checkbox"/> Authorized Generic	*If Authorized Generic, other section fields are not applicable

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

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input type="checkbox"/> Yes
Is product exempt from DSCSA?	<input type="checkbox"/> No
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	<input type="checkbox"/> No
Is FDA paid by manufacturer's exclusive distributor?	<input type="checkbox"/> No
Has FDA granted waiver/exception/exemption for product?	<input type="checkbox"/>
If yes, attach documentation from FDA.	
GLN:	
GCP:	
If yes, was original product purchased direct from mfr?	<input type="checkbox"/>
Provide source manufacturer for repackaged product	

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Depth	Width	Height	Volume (Cube)	Saleable # Pieces
Box/Carton/Bundle/Inner Pack:	7.116	11.26	7.64	4.92	423.24989	300
Case:	30.46	15.94	12.4	11.22	2217.7003	1200
Pallet:	Sea-855.449 Air-1129.58	48	40	Sea-38.9 Air-50.12	4688 Air-96	Sea-32400 Air-43200

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	50		00355150359509	
<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack	300		30355150359500	
<input checked="" type="checkbox"/> Case	1200		50355150359504	
<input checked="" type="checkbox"/> Pallet	43200		70355150359508	

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$225.00	Whsl. Code #:	
As of date:	10/24/2022	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:

D.Venkata Surender Reddy