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

Version 2021 | Introduction Type: New Item | [ ] Final Version | Date: 3/29/2023

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):	216437
Medical Device Class, if applicable:	
DUNS:	968961354
Proprietary Name (If Applicable) and Established Name:	Regadenoson Injection 0.4 mg per 5 mL
Selling Unit NDC:	55150-0443-01
Unit of Use NDC:	55150-0443-01
UPC:	355150443017
UDI	
CVX Code:	
MVX Code:	
Description:	Regadenoson Injection 0.4 mg per 5 mL (0.08 mg/mL) Single-Dose prefilled Syringe(1's)
Active Ingredient(s):	Regadenoson
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:	adenosine receptor agonist

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…	Neither
Orphan Drug Status	
FDA Approval Status	
Allergens Present	
Country of Origin	India
Is this product covered under the Trade Agreements Act (TAA)?	No

PRODUCT DESCRIPTION INFORMATION

Size:	1 PFS
Strength:	0.4 mg per 5 mL (0.08 mg/mL)
Dosage Form:	Solution
Product Shape:	PFS
Product Color:	Clear
Product Imprint:	

FOR GENERIC DRUG PRODUCTS

[ ] Authorized Generic *If Authorized Generic, other section fields are not applicable

I. Orange Book Rating:	AP
II. Generic Equivalent to What Brand?:	Lexiscan Injection

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?	
If yes, attach documentation from FDA.	
GLN:	
GCP:	
If yes, was original product purchased direct from mfr?	
Provide source manufacturer for repackaged product	

GTIN AND HIBCC PRODUCT INFORMATION

	Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
x	Item/Each	1		00355150443017	
	Box/Carton/Bundle/Inner Pack	12		30355150443018	
	Case	24		50355150443012	
	Pallet	2880		70355150443016	

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?	No
Is this product to be shipped to customers on dry ice?	No

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?	No	
Special returns requirements for this product?	No	
d. Store product (unit of sale) upright?	No	
Protect product (unit of sale) from light?	No	
e. Shelf life:	24	Months
Initial shelf life at launch (if different):		Months

ORDER INFORMATION

Unit of Sale	
	Bottle
x	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 box of 1 PFS (Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity? Yes

If Yes, how many of which package type?

1	Each
	Inner/Carton/Pack
	Case

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer? 1 PFS (Write-in, e.g. 1 Vial)

Rx billing unit to pharmacy:

x	Each
	Gram
	Milliliter

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.) Depth	Width	Height	Volume (Cube)	Saleable # Pieces
Item/Each:	0.10167	6.5	1.18	1.57	12.0419	1
Box/Carton/Bundle/ Inner Pack:	1.448	5.55	5.55	7.48	230.403	12
Case:	3.815	11.811	6.89	9.055	736.876	24
Pallet:	490.825	48	40	50.28	96537.6	2880

COST INFORMATION

Regular Cost	
Invoice Cost (WAC) ($)	$150.00
As of date:	3/29/2023

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: D.Venkata Surender Reddy