



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

Version 2021

Introduction Type: New Item

Final Version

Date: 11/23/2022

PRODUCT INFORMATION	
Company Name:	Eugia US LLC (f/k/a AuroMedics Pharma LLC)
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	213873
Medical Device Class, if applicable:	
DUNS:	968961354
Proprietary Name (if Applicable) and Established Name:	Prochlorperazine Edisylate Injection USP, 10 mg/2 mL (5 mg/mL) Multiple-Dose Vials
Selling Unit NDC:	55150-360-25
Unit of Use NDC:	55150-360-01
UPC:	355150360253
UDI	
CVX Code:	
MVX Code:	
Description:	Prochlorperazine Edisylate Injection, USP, 10 mg/2 mL (5 mg/mL) 25 x 2 mL Multiple-dose vials
Active Ingredient(s):	Prochlorperazine Edisylate
URL for Additional Product Information:	
Address:	279 Princeton-Hightstown Road
City:	East Windsor
Key Contact:	
Phone Number:	888-238-7880
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)	
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"/> 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?	<input type="checkbox"/> No
Special returns requirements for this product?	<input type="checkbox"/> No
d. Store product (unit of sale) upright?	<input type="checkbox"/> Yes
Protect product (unit of sale) from light?	<input type="checkbox"/> Yes
e. Shelf life:	24 Months
Initial shelf life at launch (if different):	

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	
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:	25 x 2 mL MDV
preservative-free?	<input type="checkbox"/> No	Strength:	10 mg per 2 mL (5 mg/mL)
correctional institution block?	<input type="checkbox"/> No	Dosage Form:	LIQUID
opioid?	<input type="checkbox"/> No	Product Shape:	Vial Pack
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	55150-360-25
<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?:	Compazine 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:
Multi vials (25s) carton	<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 product sold by manufacturer's exclusive distributor?	<input type="checkbox"/> No
Has FDA granted waiver/exception/exemption for product?	<input type="checkbox"/> No
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:						0
Case:	25.454	15.551	12.007	9.645	1800.9227	1200
Pallet:	Sea: 949.400 Air: 1178.490	48	40	43.58	Sea: 83673.6 Air: 102201.6	Sea: 43200 Air: 54000

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	25		00355150360253	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	1200		50355150360258	
<input checked="" type="checkbox"/> Pallet	54000		70355150360252	

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$225.00	Whsl. Code #:	
As of date:	11/23/2022	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