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

Version 2024 | **Introduction Type:** Post Launch Change | ☐ Final Version | **Date:** 6/4/2025

PRODUCT INFORMATION

Company Name:	Eugia US LLC
Application:	ANDA
Application Number for NDA/ANDA/BLA; PMA/510(k):	203701
Medical Device Class, if applicable:	
DUNS:	968961354
Proprietary Name (If Applicable) and Established Name:	Acyclovir Sodium Injection
Selling Unit NDC:	55150-155-20
Unit of Use NDC:	55150-155-20
UPC:	355150155200
UDI:	
CVX Code:	
MVX Code:	
Description:	Acyclovir Sodium Injection 1000mg/20mL (50mg/mL) [20mL Single Dose Vial]
Active Ingredient(s):	Acyclovir USP
URL for Additional Product Information:	https://eugiaus.com/products/
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:	ANTIVIRAL

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	India
Is this product covered under the Trade Agreements Act (TAA)?	No

PRODUCT DESCRIPTION INFORMATION

Size:	10 x 20 mL Single-Dose Vials
Strength:	1,000 mg per 20 mL(50 mg/mL)
Dosage Form:	Liquid
Product Shape:	Vial Pack
Product Color:	
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?:	ZOVIRAX®

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	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
x	Item/Each		10		00355150155200	
	Box/Carton/Bundle/Inner Pack					
x	Case		100		60355150155202	
x	Pallet				70355150155209	

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

b. Contact for temperature excursion questions:

Name:	Eugia US Customer Service
Number:	888-238-7880
Group E-mail:	CustomerService@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?	Yes
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		What is the NDC selling unit?
	Bottle		1 Box of 10 Vials
x	Box/Carton		(Write-in, e.g. 1 Box of 10 Vials)
	Ampule		
	Glass		**Minimum order quantity?** Yes
	Tube		
	Vial Liquid Sgl		**If Yes, how many of which package type?**
	Vial Liquid Multi		
	Vial Powder Sgl		Each
	Vial Power Multi		Inner/Carton/Pack
	Other: Write In	1	Case

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?	10 Vials	
(Write-in, e.g. 1 Vial)		
Rx billing unit to pharmacy:	x Each	
	Gram	
HCPCS J-Code:	Milliliter	

ITEM AND PACKING INFORMATION

	Weight Lbs.	Depth	Width	Height	Volume (Cube)	Saleable # Pieces
Item/Each:	1.02513	6.5	2.68	2.76	48.079	10
Box/Carton/Bundle/Inner Pack:					0	
Case:	11.795	14.763	7.677	7.086	803.10	100
Pallet:	1271.462	48	40	54.61	104851.2	10500

Dimensions (US msmts.)

COST INFORMATION

		WHOLESALER USE ONLY:	
Regular Cost		**Vendor #:**	
Invoice Cost (WAC) ($)	$210.00	**Whsl. Code #:**	
		Fineline Code:	
As of date:	9/10/2025		

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

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

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?
- d. Does this product require special clean-up instructions? — No
  - (If yes, attach SDS with special instructions.)
- e. Does the product contain DEHP?

Is this product regulated for shipment by DOT? — No
(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?

Is this product regulated for shipment by IATA? — No
(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?

Is the product restricted for air shipment? If so, indicate restriction: — No
- 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?
___ (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#

ADD'L STORAGE INFORMATION

Is the Product…

Controlled Substance?	No	Controlled Substance Code	
Controlled by State(s)?	No	Listed Chemical (List I or II)	No
ARCOS Reportable?	No	If yes, indicate which:	
Schedule No.		Is it a scheduled listed chemical product?:	No

CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices — Yes

Restricted to retail pharmacy only:

Restricted to hospital, clinics, and physician offices only:
Restricted from US territories? (explain in comments)

Comments:

SDS Hazard Classification

- Organic
- Inorganic
- Steroid/Androgen
- Corrosive
- Oxidizer
- Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level: — No

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?
If Yes, is it managed with a pharmacy registry?
Website URL:

Med Guide Required — No
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 _____ NCPDP#: _____
- by Supplier: _____ NPI #: _____

Comments

Registry:
- Registry Program Contact Name: _____ Phone: _____
- Comments

RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

Is product returnable for credit: — Yes
URL/Link to returns policy:
https://eugiaus.com/policies/return-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:

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

HDA

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?