



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

Version 2021

Introduction Type:  New Item

Final Version

Date: 09.05.2023

## PRODUCT INFORMATION

**Company Name:** Eugia US LLC **Application:** ANDA

**Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):** \_\_\_\_\_

**Medical Device Class, if applicable:** \_\_\_\_\_

**DUNS:** \_\_\_\_\_

**Proprietary Name (If Applicable) and Established Name:** \_\_\_\_\_

**Selling Unit NDC:** 55150-313-01 **Unit of Use NDC:** 55150-313-01 **UPC:** 355150313013

**UDI** \_\_\_\_\_ **CVX Code:** \_\_\_\_\_ **MVX Code:** \_\_\_\_\_

**Description:** Methylprednisolone Acetate Injectable Suspension, USP 400mg/10mL (40mg/mL) (MDV) (MONO)

**Active Ingredient(s):** \_\_\_\_\_

**URL for Additional Product Information:** \_\_\_\_\_

**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:** \_\_\_\_\_

## SPECIAL HANDLING AND STORAGE REQUIREMENTS\*

**a. Temperature – Indicate the USP temperature range for this product.**

Temperature Range:  \_\_\_\_\_

Other Temperature Range Requirement (write in): \_\_\_\_\_

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:** \_\_\_\_\_

**Number:** \_\_\_\_\_

**Group E-mail:** \_\_\_\_\_

**c. Special regulations for product in any states?**

Special returns requirements for this product?

**d. Store product (unit of sale) upright?**

**Protect product (unit of sale) from light?**

**e. Shelf life:**  Months

Initial shelf life at launch (if different):  Months

## ADDITIONAL PRODUCT INFORMATION

**The product is?**

a legend device?

if yes, enter class # \_\_\_\_\_

a product kit?

if yes, list NDCs of component parts reverse numbered? \_\_\_\_\_

co-licensed?

latex-free?

preservative-free?

correctional institution block?

opioid?

Cannabinoid?

If Unit Dose, is item bar coded to unit dose for hospital scanning?

If Unit Dose, indicate NDC here: \_\_\_\_\_

**Is the Product... Orphan Drug Status?**

**FDA Approval Status** \_\_\_\_\_

**Allergens Present** \_\_\_\_\_

Country of Origin:

Is this product covered under the Trade Agreements Act (TAA)?

**PRODUCT DESCRIPTION INFORMATION**

**Size:** 1 Multi Dose Vial

**Strength:** 400mg per 10mL

**Dosage Form:** Solution

**Product Shape:** \_\_\_\_\_

**Product Color:** \_\_\_\_\_

**Product Imprint:** \_\_\_\_\_

## ORDER INFORMATION

**Unit of Sale**

Bottle

Box/Carton

Ampule

Glass

Tube

Vial Liquid Sgl

Vial Liquid Multi

Vial Powder Sgl

Vial Powder Multi

Other: Write In \_\_\_\_\_

**What is the NDC selling unit?** 55150-313-01

(Write-in, e.g. 1 Box of 10 Vials)

**Minimum order quantity?**

**If Yes, how many of which package type?**

Each

Inner/Carton/Pack

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?** \_\_\_\_\_

(Write-in, e.g. 1 Vial)

**Rx billing unit to pharmacy:**

Each

Gram

Milliliter

## DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

**Does supplier meet DSCSA definition of manufacturer?**

**Is product exempt from DSCSA?**

**If yes, select exemption:** \_\_\_\_\_

**Other exemption - Write in:** \_\_\_\_\_

**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.** \_\_\_\_\_

**GLN:** \_\_\_\_\_

**GCP:** \_\_\_\_\_

**If yes, was original product purchased direct from mfr?**

**Provide source manufacturer for repackaged product** \_\_\_\_\_

## ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.08506	1.42	1.42	2.56	5.162	1 vial
Box/Carton/Bundle/Inner Pack:	5.7641	15.2	9.49	2.99	431.302	60 vials
Case:	25.6002	20.079	15.945	7.677	2457.866	240 vials
Pallet:	Air-801.0456 Sea-673.0446	48	40	51.06.39	Air-80033.2 Sea-83308.8	Air-7200 vials Sea-6000

## 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		00355150313013	
<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack	60		30355150313014	
<input checked="" type="checkbox"/> Case	240		50355150313018	
<input checked="" type="checkbox"/> Pallet	7200		70355150313012	

## COST INFORMATION

**Regular Cost** \_\_\_\_\_

**Invoice Cost (WAC) (\$)** \_\_\_\_\_

As of date: \_\_\_\_\_

**WHOLESALE USE ONLY:**

**Vendor #:** \_\_\_\_\_

**Whsl. Code #:** \_\_\_\_\_

**Fineline Code:** \_\_\_\_\_



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PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: Eugia US LLC		Application: ANDA		a. Temperature – Indicate the USP temperature range for this product.			
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):				Temperature Range: <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/>			
Medical Device Class, if applicable:				Other Temperature Range Requirement (write in): <input type="text"/>			
DUNS:				Notes: <input type="text"/>			
Proprietary Name (If Applicable) and Established Name:				Is this product to be shipped to customers on ice? <input type="checkbox"/> No			
Selling Unit NDC: 55150-314-01		Unit of Use NDC: 55150-314-01		UPC: 355150314010		Is this product to be shipped to customers on dry ice? <input type="checkbox"/> No	
UDI:		CVX Code:		MVX Code:			
Description: Methylprednisolone Acetate Injectable Suspension, USP 400mg/5mL ( 80mg/mL) (MDV) (MONO)				b. Contact for temperature excursion questions:			
Active Ingredient(s):				Name: <input type="text"/>			
URL for Additional Product Information:				Number: <input type="text"/>			
Address: 279 Princeton-Hightstown Road		Address 2:		Group E-mail: <input type="text"/>			
City: East Windsor		State: NJ		Zip: 08520			
Key Contact:		Email:		c. Special regulations for product in any states?			
Phone Number: 888-238-7880		Fax: 732-355-9449		Special returns requirements for this product? <input type="text"/>			
Product Therapeutic Classification:				d. Store product (unit of sale) upright? <input type="text"/>			
				Protect product (unit of sale) from light? <input type="text"/>			
				e. Shelf life: <input type="text" value="24"/> Months			
				Initial shelf life at launch (if different): <input type="text"/> Months			
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
The product is? a legend device? <input type="checkbox"/>		Is the Product... <input type="checkbox"/>		Size: 1 Multi Dose Vial			
if yes, enter class # <input type="text"/>		Is the Product... <input type="checkbox"/>		Strength: 400mg per 5mL			
if yes, list NDCs of component parts reverse numbered? <input type="text"/>		Orphan Drug Status <input type="checkbox"/>		Dosage Form: Solution			
if yes, list NDCs of component parts co-licensed? <input type="text"/>		FDA Approval Status <input type="text"/>		Product Shape: <input type="text"/>			
latex-free? <input type="checkbox"/>		Allergens Present <input type="text"/>		Product Color: <input type="text"/>			
preservative-free? <input type="checkbox"/>		Country of Origin: India		Product Imprint: <input type="text"/>			
correctional institution block? <input type="checkbox"/>		Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> No					
opioid? <input type="checkbox"/>							
Cannabinoid? <input type="checkbox"/>							
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/>							
If Unit Dose, indicate NDC here: <input type="text"/>							
ORDER INFORMATION							
Unit of Sale				What is the NDC selling unit?			
<input checked="" type="checkbox"/> Bottle				55150-314-01			
<input type="checkbox"/> Box/Carton				(Write-in, e.g. 1 Box of 10 Vials)			
<input type="checkbox"/> Ampule				Minimum order quantity? <input type="text"/>			
<input type="checkbox"/> Glass							
<input type="checkbox"/> Tube				If Yes, how many of which package type?			
<input type="checkbox"/> Vial Liquid Sgl				<input checked="" type="checkbox"/> Each			
<input type="checkbox"/> Vial Liquid Multi				<input type="checkbox"/> Inner/ Carton/Pack			
<input type="checkbox"/> Vial Powder Sgl				<input type="checkbox"/> Case			
<input type="checkbox"/> Vial Power Multi							
<input type="checkbox"/> Other: Write In <input type="text"/>							
PHARMACY ORDER / BILL UNIT							
Rec. sell unit to customer? <input type="text"/>				Rx billing unit to pharmacy:			
(Write-in, e.g. 1 Vial)				<input type="checkbox"/> Each			
				<input type="checkbox"/> Gram			
				<input type="checkbox"/> Milliliter			
ITEM AND PACKING INFORMATION							
	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces	
		Depth	Width	Height			
Item/Each:	0.07606	1.42	1.42	2.56	5.162	1 vial	
Box/Carton/Bundle/Inner Pack:	5.2241	15.2	9.49	2.99	431.302	60 vials	
Case:	23.4402	20.079	15.945	7.677	2457.866	240 vials	
Pallet:	Air-736.2456 Sea-619.0446	48	40	Air- 51.06.39 Sea-43.39	Air-88033.2 Sea- 83308.8	Air-7200 vials Sea- 6000	
GTIN AND HIBCC PRODUCT INFORMATION				COST INFORMATION			
Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14			
<input checked="" type="checkbox"/> Item/Each	1		00355150314010				
<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack	60		30355150314011				
<input checked="" type="checkbox"/> Case	240		50355150314015				
<input checked="" type="checkbox"/> Pallet	7200		70355150314019				
WHOLESALE USE ONLY:				Regular Cost <input type="text"/>			
Invoice Cost (WAC) (\$)				Vendor #: <input type="text"/>			
As of date: <input type="text"/>				Whsl. Code #: <input type="text"/>			
				Fineline Code: <input type="text"/>			

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