

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

Version 2020						Introduction Type:	New Item		Final Vers	on		Date:	3/19	9/2021	
			PRODUCT INFORMATI	ION					SPECIA	L HANDLING AND STO	DRAGE REQU	IREMENTS*			
Company Name: Amneal Pharmaceuticals LLC Application: ANDA Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 210043									a. Temperature – Indicate the USP temperature range for this product. Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)						
DUNS:	827748190	iiro ro(k)(iiica acti	1		Range Requirement		3 ana 20 0 (0	,							
Proprietary Name (If Applicable)		me: MethylF	PREDNISolone Acetate Injec	table Suspension.	. USP 40mg	ı/mL		1	(write in)	Kange Kequirement					
Selling Unit NDC:	70121-1573-1	,	Unit of Use NDC:		,		2115731-1		Notes						
UDI			CVX Code:			MVX Code:									
Description:	Is this product to be shipped to customers on ice? Is this product to be shipped to customers on dry ice? No														
Active Ingredient(s):	h Contact for	temperature excurs		,			_								
URL for Additional Product Infor	mation:	b. Contact for	Name:	sion questions:											
Address:	400 Crossing Blvd. Third Floor Address 2:								Number: 877-835-5472 option 1						
City:	Bridgewater]	Group E-mail:										
Key Contact:	866-525-7270								NI-						
Phone Number: Product Therapeutic Classification		Corticosteroid			Fax:	866-525-7271		c. Special regi	ulations for product	in any states? irements for this product	2		No No	-	
Froduct Therapeutic Classification	JII.	Corticosteroid							Special returns requ	irements for this product			INU	_	
	ADDITIO	NAL PRODUCT INF	ORMATION	d. Store produ	ıct (unit of sale) upı	ight?			Yes						
The product is?			Is the Product	Direct-Ship Only	,			·		nit of sale) from light?			No	=	
a legend device?		No	Is the Product			Size:	1mL Single-Dose Vial	e. Shelf life:	(a.				24	Months	
if yes, enter class #			Orphan Drug Status			Size:			Initial shelf life at la	nunch (if different):				Months	
a product kit?		No		40mg/mL			ORDER INFO	MATION							
if yes, list NDCs of component parts			FDA Approval Status				Injectable Suspension			ORDER INFO	RWATION				
reverse numbered?		No				Dosage Form:	injudiable Casponelen		Unit of Sale		What is the	NDC selling	g unit?		
co-licensed?		No	Allergens Present						Bottle			1mL Single-I			
latex-free?		Yes				Product Shape:			x Box/Carto	ı	(Write-in, e	e.g. 1 Box of 1	10 Vials)		
preservative-free?		Yes					white to off white		Ampule Glass		Minimum			Vee	
correctional institution block? opioid?		No No				Product Color:	white to off-white homogeneous		Tube		Willimum	order quantit	y r	Yes	
Cannabinoid?		No	Country of Origin	India		Product Imprint:			Vial Liquid	Sgl					
If Unit Dose, is item bar coded to	unit dose for hospital					Product imprint:			Vial Liquid				nich package	type?	
scanning?			Is this product covered un						Vial Powd		240	Each			
If Unit Dose, indicate NDC here:			Trade Agreements Act (T/	AA)? <u>No</u>	0				Vial Powe Other: Wri			Inner/Carto Case	n/Pack		
			FOR GENERIC DRUG PRO	DUCTS				J	0.11011 7711						
	Authorized Generic *If Authorized Generic, other section							PHARMACY ORDER / BILL UNIT							
I. Orange Book Rating:									Rec. sell unit to customer? Rx billing unit to pharmacy:						
II. Generic Equivalent to What Br	and?:	DEPO MEDROL						(Write-in, e.g.	4 \/iel\			Each Gram			
		DRUG SUPPLY	CHAIN SECURITY ACT (D	SCSA) INFORMA	ATION			(vviite-iii, e.g.	i viai)			Milliliter			
Does supplier meet DSCSA defin Is product exempt from DSCSA?		rer?	Yes No	GLN:						ITEM AND PACKING	INFORMATIO	N			
If yes, select exemption:				_					Weight	Dimen	sions (US ms	mts.)	Volume	# Pieces:	
Other exemption - Write in:									weight	Depth	Width	Height	(Cube)	# Pieces:	
Is product repackaged?			No			nal product purchased		Item/Each:	14.74	gm 1.1875"	1.5625"	1.8125"		1	
Is product sold by manufacturer Has FDA granted waiver/exception			No No	_	from mfr?	cumentation from FDA.		Box/Carton/B							
That I DA granted waiver/exception	on exemption for pr		110	yes,	, attaon aot	Junichtation Hom 1 DA.		Inner Pack:	undic,						
		GTIN	AND HIBCC PRODUCT IN	FORMATION				Case:	8.31	os 16.0625"	8.0625"	8.625"		240	
Colooble Hair of Manage		O it.	LUDOO		6711		Heiradilla OTNI 44	D-W-/	0.01	10.0320	0.0020	0.020			
Saleable Unit of Measure		Quantity	HIBCC		GTIN-1	14 121157311	Unit of Use GTIN-14	Pallet:	621	bs 40.25"	32.25"	65.375"		70	
Box/Carton/Bundle/Inner Pack					30370	.207011			l .						
X Case								COST INFORMATION WHOLESALER USE ONLY:							
Pallet	_														
	-							Regular Cost Invoice Cost (WAC) (\$)	***	Vendor #: Whsl. Cod	o #·			
								invoice cost (··· AO) (#)	\$9.6	Fineline Co				
								As of date:	7/7/2020						
			Attach copy of SAFETY DAT	A SHEET (SDS)	or non haza		RT, LABEL AND PHOTO OF	PRODUCT PACK		DE.					
*Please provide any additional in	formation on page	2.				See new p. 3 for Desig	nated Drop Ship Only.		Signature:						



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For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION Is this product (check all that apply): a. Cytotoxic? SDS Hazard Classification No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? No Organic Corrosive Is the product a CA Prop 65 reproductive toxicant? No Oxidizer Inorganic Does the product label bear a CA Prop 65 warning? No Steroid/Androgen Contact Hazard Yes Aerosol Class; Identify NFPA Storage Level: c. Contact Hazard? d. Does this product require special clean-up instructions? No Is the product a NIOSH hazardous drug? (If yes, attach SDS with special instructions.) No e. Does the product contain DEHP? No If yes, indicate which: Is this product regulated for shipment by DOT? No (if yes, answer a-e below and provide SDS) **Hazardous Waste Identificatio** a. UN/Identification Number b. Proper Shipping Name EPA Hazardous Waste Code: Waste Characteristics c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? Yes Is this product regulated for shipment by IATA? REMS or REGISTRY RESTRICTIONS (if yes, answer a-e below and provide SDS) Is there a REMS on this product? No a. UN/Identification Number If Yes, is it managed with a pharmacy registry? Website URL: b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? Med Guide Required Is the product restricted for air shipment? If so, indicate restriction: Limited Distribution Requirement x Passenger Comments / Details: (For example, iPledge program?) Cargo Passenger & Cargo Is this a reportable quantity? REMS: RQ Threshold: REMS Program Manager Name: Phone Is this a marine pollutant? Supplier Manages REMS registry exclusively: Is this product shipped utilizing an authorized DOT exception or Special Permit? Wholesale distributor support: No (if yes, identify method below) Provider Name: DEA #: Limited Quantity Site Enrollment Number assigned PCPDP# Consumer Commodity, ORM-D NPI#: by Supplier: Small Quantity (49 CFR 173.4) Special Permit: DOT-SP Comments Special Provision (listed in Column 7 of 49 CFR 172.101); SP# Registry: Phone: Registry Program Contact Name: ADD'L STORAGE INFORMATION Comments Is the Product... RETURN INSTRUCTIONS Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) No 866-525-7270 ARCOS Reportable? No If yes, indicate which: Contact tel. # if product received damaged: Schedule No. Is it a scheduled listed chemical product?: No Is product returnable for credit: CLASS OF TRADE RESTRICTION: URL/Link to returns policy: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes Restricted to retail pharmacy only: No Special regulations or returns requirements for this product in certain states? No Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) No If so, which states? Other requirements? Comments? Comments: MISCELLANEOUS NOTES and/or Image of Product Barcode



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FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing							
Purchase orders may be accepted by: a. EDI b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Fax Number: Fax Number: Phone No.: Site Address:	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:							
Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone: Expedited Freight Charges or Other Designated Drop Ship Fees:	Ships regular ground for 3-10 days receipt: Overnight and Priority Overnight PO Processing							
Expedited freight fees billed with each order:	Overnight receipt available:							
Drop Ship service fee billed with each order:	PO Receipt cut off time:							
Drop Ship miscellaneous fees billed: Comments:	Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday							
Class of Trade Restriction:	PO Receipt Cut off time:							
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:	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: Fax: EDI: Overnight Fees apply: Other fees apply:							
Other Data Information Required to Process PO:	Return Instructions							
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:	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?							