

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

Version 2020				Introduction Type:	New Item		Final Version			Date:	3/19/	2021
		PRODUCT INFORMATION					SPECIAL HAN	DLING AND STOR	AGE REQUI	REMENTS*		
Company Name:	cate the USP tempe	the USP temperature range for this product.										
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 210043 Temperature Range Controlled Room - between 20 and 25 C (68° - 77° F)												
DUNS:	827748190	b					emperature Range F	Requirement				
Proprietary Name (If Applicable) a Selling Unit NDC:	and Established Name: 70121-1574-5	MethylPREDNISolone Acetate Injectable S Unit of Use NDC:	uspension, USP 80mg	•	02115745-8		vrite in)					
UDI	70121-1574-5	CVX Code:		MVX Code:	J2115745-6	Notes						
Description: Methylprednisolone Acetate Injectable Suspension, USP is supplied as a white to off-white homogenous suspension in single-dose vial. Is this product to be shipped to customers on ice? No												
Description	inetry produced on a restate in	Is this product to be shipped to customers on dry ice? No										
Active Ingredient(s):	Methylpre											
LIPL for Additional Broduct Inform	notion	b. Contact for temper Name:		estions:								
Address:	JRL for Additional Product Information: Address: 400 Crossing Blvd. Third Floor Address 2:						Number: 877-835-5472 option 1					
City:	Bridgewater State: NJ Zip: 08807						E-mail:			•		
Key Contact:			Email:						-			-
Phone Number:	866-525-7270		Fax:	866-525-7271		c. Special regulations					No	
Product Therapeutic Classificatio	Corticoste	froid				Specia	returns requirement	s for this product?			No	
ADDITIONAL PRODUCT INFORMATION PRODUCT DESCRIPTION INFORMATION d. Store product (unit of sale) upright? Yes												
The product is?		Is the Product Direct	t-Ship Only				t product (unit of sa	ale) from light?			No	
a legend device?	No	Is the Product		Size:	25 x 1mL Single-Dose	e. Shelf life:		, .			24	Months
if yes, enter class #		Orphan Drug Status			Vials	Initial	shelf life at launch (i	if different):				Months
a product kit? if yes, list NDCs of	No	FDA Approval Status		Strength:	80mg/mL				IATION			
component parts				Dosage Form:	Injectable Suspension							
reverse numbered?	No	_		Dosage Form.		Unit of				NDC selling		
co-licensed? latex-free?	No	Allergens Present				x	Bottle			25 x 1mL Sing g. 1 Box of 10		S
preservative-free?	Yes Yes	-		Product Shape:			Box/Carton Ampule		(write-iii, e.	g. i bux ui ii	vidis)	
correctional institution block?	No			Product Color:	white to off-white		Glass		Minimum o	rder quantity	?	Yes
opioid?	No			Floader Color.	homogeneous		Tube					
Cannabinoid?	No No	Country of Origin India		Product Imprint:			Vial Liquid Sgl Vial Liquid Multi		lf Vaa haw	many of whi		6 m a 2
If Unit Dose, is item bar coded to u scanning?	Init dose for nospital	Is this product covered under the					Vial Powder Sql			many of whi Each	ch package	typer
If Unit Dose, indicate NDC here:		Trade Agreements Act (TAA)?	No				Vial Power Multi			Inner/Carton	/Pack	
		FOR GENERIC DRUG PRODUCTS					Other: Write In			Case		
	-											
			Autho	prized Generic *If Aut	horized Generic, other section	PHARMACY ORDER / BILL UNIT						
I. Orange Book Rating:	AB				are not applicable	Rec. sell unit to custo	omer?		Rx billing u	nit to pharm	acv:	
II. Generic Equivalent to What Bra		DROL						1		Each		
						(Write-in, e.g. 1 Vial)		-		Gram		
	DRUG	SUPPLY CHAIN SECURITY ACT (DSCSA)	INFORMATION						ļ	Milliliter		
Does supplier meet DSCSA defini	ition of manufacturer?	Yes	GLN:				ITEM	AND PACKING IN	FORMATIO	N		
Is product exempt from DSCSA?		No										
If yes, select exemption:							Weight Lbs.		ons (US msn		Volume	# Pieces:
Other exemption - Write in:		No	If Yee wee enigh	nal weather work and		Kem/Each		Depth	Width	Height	(Cube)	
Is product repackaged? Is product sold by manufacturer's	s exclusive distributor?	No No	direct from mfr?	nal product purchased		Item/Each:	181.44 gm	3.625"	5.625"	1.8125"		1
Has FDA granted waiver/exceptio		No		cumentation from FDA.		Box/Carton/Bundle/						
						Inner Pack:						
		GTIN AND HIBCC PRODUCT INFORM	ATION			Case:	11.9 lbs	15.375"	12"	6.625"		24
Saleable Unit of Measure	Quantity	HIBCC	GTIN-	14	Unit of Use GTIN-14	Pallet:	000.0 "	10 777		04.000		70
X Item/Each	1			121157458			896.8 lbs	42.75"	36"	64.625"		72
Box/Carton/Bundle/Inner Pack		-		101157150								N.
X Case Pallet	24	-	50370	121157453		co	ST INFORMATION			WHOLESALI	ER USE ONL	
	7 H					Regular Cost			Vendor #:			
						Invoice Cost (WAC) (\$)	\$408.00	Whsl. Code			
	-	_				As of date:	7/7/2020		Fineline Co	de:		
						AS OF GALE.	11112020					
		Attach copy of SAFETY DATA SHE	ET (SDS) or non haza	rd letter, PACKAGE INSE	RT, LABEL AND PHOTO OF I	PRODUCT PACKAGING	and BARCODE.					
*Please provide any additional inf	formation on page 2.				nated Drop Ship Only.	Signat						

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Version 2020 For Designated Drop Ship Only Products, Please Use Page 3									
MATERIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION								
Is this product (check all that apply):									
a. Cytotoxic? No	SDS Hazard Classification								
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	Inorganic Oxidizer								
Does the product label bear a CA Prop 65 warning? No	Steroid/Androgen X Contact Hazard								
c. Contact Hazard? Yes	Aerosol Class; Identify NFPA Storage Level:								
d. Does this product require special clean-up instructions? No	Is the analysis of NOCU become down?								
(If yes, attach SDS with special instructions.)	Is the product a NIOSH hazardous drug? No								
e. Does the product contain DEHP? No No No	If yes, indicate which:								
(if yes, answer a-e below and provide SDS)									
a. UN/Identification Number	Hazardous Waste Identification								
b. Proper Shipping Name									
c. DOT Hazard Class	EPA Hazardous Waste Code: Waste Characteristics								
d. Packing Group	Trade Oranaciensita								
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?								
b. Proper Shipping Name	Website URL:								
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?)								
	Comments / Details. (For example, intege program?)								
Cargo Passenger & Cargo									
Is this a reportable quantity? No	REMS: No								
RQ Threshold:	REMS Program Manager Name: Phone:								
Is this a marine pollutant? No	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	by Supplier: NPI #:								
Small Quantity (49 CFR 173.4)									
Special Permit; DOT-SP	Comments								
Special Provision (listed in Column 7 of 49 CFR 172.101);									
SP#	Registry: No								
	Registry Program Contact Name: Phone:								
ADD'L STORAGE INFORMATION	Comments								
Is the Product									
Controlled Substance? No Controlled Substance Code	RETURN INSTRUCTIONS								
Controlled by State(s)? No Listed Chemical (List I or II) No									
ARCOS Reportable? No If yes, indicate which:	Contact tel. # if product received damaged: 866-525-7270								
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								
Restricted to hospital, clinics, and physician offices only: No	product in certain states?								
Restricted from US territories? (explain in comments) No	If so, which states? Other requirements? Comments?								
Comments:									
MISCELLANEC	DUS NOTES and/or Image of Product Barcode:								



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Version 2020 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 Fax Number: c. Fax Fax Number: d. Phone only Phone No.: e. Supplier Web Site only Site Address: Minimum Order Quantity:	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:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:	Overnight receipt available:
	Priority Overnight receipt available:
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:	PO Receipt Cut off time: PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: PO Receipt Cut off time: Pone: Order receipt method: Phone: Fax: Fax #: EDI: Overnight Fees apply: Other fees apply: Image: Content of the temperature
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	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?