11.50	2444
	DMA

Standard Pharmaceutical Product Information

CHDMA Standard Pharm	aceutical Prod	duct Infor	mation	ı Item □ Pr	omotion/Dea	al Open S	Stock Pos	st Launch Ch	Date:		29-07-2014
PRODU	CT INFORMATION				-		LING AND S			ENTS	
Manufacturer/Broker Name: Strides	OT IN ORMATION	Number:		a Temper			P temperatur				
Rx Product Name: Imiquimod	Cream, 5%		NDA (ANDA	a. remper			25 and -10 C	_	-	ι.	
Product ID Number: V NDC 64380-773-0	•	,	J	1			id 8 C (36° –		•		
Serialized? • Yes • No How?		Pallet C	ase Item	1			nd 15 C (46°	•	a		
	V ZD NID	railet C	ase Item	-			•	•	_		
Description: Imiquimod Cream, 5 %					iv. Contro		between 20 or excursion		-	(59° – 86°	F)
JRL for additional product information:					V. Excess	ive Heat – ab	ove 40 C (>1	04° F)]		
Address: 201 South Main Street, Su	ite 3				VI. Other 1	Temperature	Range Requii	rement	•		
City, State, Zip: Lambertville, NJ 08530						(write in)	between 4°	to 25 °C (39	to 77°F)Do		
(ey Contact: JB Davis	Email:	sales@stride	susa.com		VII. No Re	quirement	0			•	
Phone Number: 8134446299	Fax:	8133303058		b. Contact	for temper	rature excurs	sion question	ns:			
s the Product	A Drop Ship Item				Nagesh M		·		6097735004	1	
	If Yes, Schedule Nu								_	_	
ARCOS reportable? 🔲 Yes 🛛 No			Yes 💽 No	Is this p	roduct to b	e shipped to	customers	on ice?	☐ Yes □	No	
Co-Licensed? 💽 Yes 🔲 No		Repackaged?	Yes 💽 No	Is this p	roduct to b	e shipped to	customers	on dry ice?	O Ye	es 💽 I	No
Legend Device? 🔲 Yes 💽 No	Does the product of	contain DEHP?	Yes 💽 No							_	
Active ingredient, if product contains a drug	g: Imiquimod			c. Special	regulations	s for this pro	duct in certa	in states?	🔲 *Ye	s 💽 N	D
Country of Origin: Italy				Special	returns rec	quirements f	or this produ	ct?	Ì*Yes 💽	No	
larmonization Code Number for Internation	nal Shipping:										
s this product a Hazardous Material or Cyto	otoxic Agent?]*Yes 🧿 N	o	d. Store p	roduct upr	ight? 🔘	Yes 💽 No)			
*If y	yes, provide additior	nal information	on page 2.	Protec	t product fi	rom light?	Yes (⊙ No	Other requi	irements?	*
Attach copy of MATERIAL SAFETY DATA	SHEET (MSDS) and	d PACKAGE II	NSERT				*Please pro	vide additio	nal informa	tion on pa	age 2.
ADDITIONAL PRODUCT INFORMATION				ITEM AND	PACKING	INFORMATION	NC				
ADDITIONAL I NODGOT INI ORMATION	Size/Strength/			Mstr.	Inner		I	Г	Dimensions		# Cases/
Product Shape Cream	Form	Unit of Sale	UPC Code	Shpr.	Case Pk	Wght. Lbs.	Cube	Case	Item	Pallet	Pallet
Product Color White to Off white cream	12's/12.5mg /Cream	Bottle	Case:	132	12	Case:	1587.6174	Depth:	Depth:	Depth:	36
Product Imprint N/A		✓ Box		(Carton)	(Sachet)	6.07		14.173	2.126	47.2441	
s there a minimum order quantity?		Glass Jar	Carton:			Carton:	1	Height:	Height:	Height:	
O Yes O No		Ampule				0.037		_	_	40.5512	
f yes, how many?		Other:	Item:			Item:	†	Width:	Width:	Width:	
Of what package type?						0.001		9.645		39.3701	
	For Generic Drug Pi	roducte									
Carton Item Chelf life: 24 Months	I. Orange Book: Rat			III Brand I	Name Equiv	valent:	Aldara®				
nitial shelf life at launch (if diff't)	II. Product Color:	iiig.	White to off white	IV. Generic			Aluaia				
(Trinto to on trinto		ST INFORM						
Whsl. Code #:		Purcha	se Allowance		oution	I	I			l	
Fineline Code:	Regular Cost (\$)			OI	ВВ	Invoice	Net Cost	Mfr's	Avg Retail	SRP (\$)	Excise Tax
s Item? Unit Dose Unit of Use	ι <u>σ</u> σσσ. (ψ)	\$	<u> </u>	\$	<u></u> %	Cost (\$)	(\$)	AWP	Price (\$)	(+)	
f Unit Dose, is item bar coded to unit dose	DZ										
or hospital scanning?	EA										
☐ Yes ☐ No	PPK										

Signature:		

HAZARDOUS MAT	ERIAL INFORMATION	
this product (check all that apply):	ERIAL INFORMATION	
Cytotoxic? Yes No		
CA Prop. 65 Carcinogen or Reproductive Toxicant?		
Carcinogen		
Reproductive Toxicant		
Both		
Warning appears on label		
Contact Hazard?		
Does this product require special clean-up instructions? () Yes () No yes, attach MSDS with special instructions		
•	SHIPPING INFORMATION	
this product regulated for shipment by the DOT 🔲 Yes 💽 No		
yes, answer a-d below and provide MSDS)		
a. DOT Hazard Class	b. UN/ID Number	
c. Packing Group	d. Inhalation Hazard?	O Yes O No
or adming group	aa.a	U les UNO
this product shipped utilizing an authorized DOT exception or Special Permit?	Yes O No	(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#		
the product restricted for air shipment?		
☐ Passenger		
☐ Cargo		
Passenger & Cargo	NEODWATION.	
ease check as appropriate for this product.	INFORMATION	
Organic Inorganic		
Antineoplastic Steroid/Androgen		
Corrosive Oxidizer		
Aerosol; Identify NFPA Storage Level:	☐ Level 3	
Precursor Chemical (Describe below):	<u></u>	
Ephedrine		
Pseudoephedrine		
Phenylpropanolamine		
☐ Iodine (≥2.2%)		
Other:		
Culoi.		
ODUCT INFORMATION	ADDITIONAL INFORM	ATION
pes this product or its components have an MSDS?		eturns requirements for this product
	otc) in certain states? If so	, which states? Other requirements?
.g., chemicals, solutions, products impregnated with solutions, batteries, drugs, ϵ tach a copy of MSDS or non-hazard letter.	in certain states: ii so	,