

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

						Introduction	Type: New Item		Final Version			Date:	2/1/2	
			PRODUCT INFORMAT	TION					SPECIAL HAND	LING AND STOR	AGE REQUIR	EMENTS*		
Company Name:	Amneal Pharmac	euticals LLC				Applica	tion: ANDA	a. Temperature -	- Indicate the USP temper	ature range for th	his product.			
Application Number for NDA/ANI	DA/BLA (drug); Pl	//A/510(k)(med device	e):	090	0576		<u> </u>			Controlled Room -		nd 25 C (68°	– 77° F)	
Medical Device Class, if applicab	ole:								,					
DUNS:	827748190							0	ther Temperature Range R	equirement				
Proprietary Name (If Applicable) a	nd Established Na	me: Nizatidi	ne Oral Solution 15mg/mL (75mg/5mL)					(write in)					
Selling Unit NDC:	60846-301-15		Unit of Use NDC:			UPC:	3-6084630115-1	N	otes					
UDI			CVX Code:			MVX Code:								
Description: Nizatidine Oral Solution 15 mg/mL is a clear, pale-yellow, peppermint flavored solution. Is this product to be shi						this product to be shipped	to customers on ic	ce?		No				
			,						this product to be shipped				No	
Active Ingredient(s):		Nizatidine									-			
								b. Contact for te	mperature excursion que	stions:				
URL for Additional Product Inform									ame:					
Address:	400 Crossing Blv	d. Third Floor				Address 2:			umber:		877-835-5472	option 1		
City:	Bridgewater				State:	NJ	Zip : 08807	Group E-mail:						
Key Contact:		Email:												
Phone Number:	866-525-7270				Fax:	866-525-7271			ations for product in any s				No	
Product Therapeutic Classification	n:	Antiulcers						S	pecial returns requirements	for this product?			No	
	4 B B I W					2222107								
	ADDIII	ONAL PRODUCT INF	ORMATION			PRODUCT	DESCRIPTION INFORMATION	d. Store product	(unit of sale) upright?				Yes	
The product is?			Is the Product	Direct-Ship C	Inly				rotect product (unit of sal	e) from light?			Yes	
a legend device?		No	Is the Product			Size:	480mL	e. Shelf life:					18	Months
if yes, enter class #			Orphan Drug Status			0.20.		ln In	itial shelf life at launch (if	different):				Months
a product kit?		No				Strength:	15mg/mL (75mg/5mL)							
if yes, list NDCs of			FDA Approval Status			_				ORDER INFORM	IATION			
component parts		No				Dosage For	m: Oral Solution		nit of Sale		What is the N	IDC colling	ıni#2□	
reverse numbered? co-licensed?		No	Allergens Present						x Bottle		1 Bottle of 48			
latex-free?		NO	Allergens Fresent					ıII –	Box/Carton		(Write-in, e.g			
preservative-free?						Product Sha	ipe:		Ampule		(write-iii, e.g	. 1 DOX 01 10	viais)	
correctional institution block?		No					Clear, pale yellow		Glass		Minimum or	ler quantity	•	Yes
opioid?		No				Product Co	or:		Tube			,		
Cannabinoid?		No	Country of Origin	USA		Due divet less			Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	init dose for		, ,			Product Imp	orint:		Vial Liquid Multi		If Yes, how n	nany of whice	h package t	ype?
hospital scanning?			Is this product covered up	nder the				'II	Vial Powder Sql		142	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (T	AA)?	Yes				Vial Power Multi			nner/Carton/	Pack	
			•						Other: Write In			Case		
			FOR GENERIC DRUG PRO	DDUCTS										
			FOR GENERIC DRUG PRO	ODUCTS										
			FOR GENERIC DRUG PRO	ODUCTS	Au	uthorized Generic	*If Authorized Generic, other		PH.	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AA		FOR GENERIC DRUG PRO	DDUCTS	Au	uthorized Generic	*If Authorized Generic, other section fields are not applicable	Rec. sell unit to		ARMACY ORDER		it to pharma	cy:	
I. Orange Book Rating: II. Generic Equivalent to What Bra		Axid	FOR GENERIC DRUG PRO	DDUCTS	Au	uthorized Generic		Rec. sell unit to		ARMACY ORDER	Rx billing un	it to pharma Each	cy:	
		Axid	FOR GENERIC DRUG PRO	ODUCTS	Au	uthorized Generic		Rec. sell unit to (Write-in, e.g. 1)	customer?	ARMACY ORDER	Rx billing un		су:	
			FOR GENERIC DRUG PRO			uthorized Generic			customer?	ARMACY ORDER	Rx billing un	Each	су:	
II. Generic Equivalent to What Bra	nd?:	DRUG SUPPLY	' CHAIN SECURITY ACT (I		RMATION	uthorized Generic			customer?□ Vial)		Rx billing un	Each Gram	су:	
II. Generic Equivalent to What Bra	nd?:	DRUG SUPPLY	CHAIN SECURITY ACT (I			uthorized Generic			customer?□ Vial)	ARMACY ORDER	Rx billing un	Each Gram	cy:	
II. Generic Equivalent to What Bra	nd?:	DRUG SUPPLY	' CHAIN SECURITY ACT (I		RMATION GLN:	uthorized Generic			customer?□ Vial)	AND PACKING IN	Rx billing un	Each Gram Milliliter	cy:	
II. Generic Equivalent to What Branch	nd?:	DRUG SUPPLY	CHAIN SECURITY ACT (I		RMATION	uthorized Generic			customer?□ Vial) ITEM	AND PACKING IN	Rx billing un	Each Gram Milliliter	Volume	Saleable #
II. Generic Equivalent to What Branch	nd?:	DRUG SUPPLY	Y CHAIN SECURITY ACT (I Yes No		GLN:		section fields are not applicable	(Write-in, e.g. 1 \	customer?□ Vial)	AND PACKING IN	Rx billing un	Each Gram Milliliter		Saleable #
II. Generic Equivalent to What Branch Branch Branch Branch Broduct exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	nd?: tion of manufactur	DRUG SUPPLY	/ CHAIN SECURITY ACT (I Yes No		GLN: GCP: If yes, was o	riginal product pui	section fields are not applicable		customer?□ Vial) ITEM Weight Lbs.	AND PACKING IN	NFORMATION Ons (US msmr	Each Gram Milliliter s.) Height	Volume	Pieces
II. Generic Equivalent to What Bra Does supplier meet DSCSA definit Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	nd?: tion of manufactur exclusive distribu	DRUG SUPPL	Y CHAIN SECURITY ACT (I Yes No No No		GLN: GCP: If yes, was o direct from n	riginal product pur	section fields are not applicable	(Write-in, e.g. 1 \times 1 \ti	vial) ITEM Weight Lbs. 610.93gm	AND PACKING IN Dimensi Depth	Rx billing un	Each Gram Milliliter	Volume	
II. Generic Equivalent to What Brain Does supplier meet DSCSA definition is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product repackaged? Has FDA granted waiver/exception	nd?: tion of manufactur exclusive distribun/exemption for pr	DRUG SUPPL	/ CHAIN SECURITY ACT (I Yes No		GLN: GCP: If yes, was o direct from n	riginal product pur	section fields are not applicable	(Write-in, e.g. 1 Write-in, e.g. 1 \text{ Write-in, e.g. 2 \text{ Write	vial) ITEM Weight Lbs. 610.93gm	AND PACKING IN Dimensi Depth	NFORMATION Ons (US msmr	Each Gram Milliliter s.) Height	Volume	Pieces
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II. Generic Equivalent to What Brain II. Generic Equivalent to What Brain II. Generic Equivalent to What Brain II. Generic Equivalent III. Generic Equivalent	nd?: tion of manufactur exclusive distribun/exemption for pr n FDA.	DRUG SUPPL'	Yes No No No No No	DSCSA) INFOR	GLN: GCP: If yes, was o direct from n Provide sour	riginal product pur fir? rce manufacturer f	section fields are not applicable	(Write-in, e.g. 1 Write-in, e.g. 1 \text{ Write-in, e.g. 2 \text{ Write	Customer? Vial) Weight Lbs. 610.93gm dle/ 16.6 lbs	AND PACKING IN Dimensis Depth 2.75*	Rx billing un NFORMATION Ons (US msm Width 2.06"	Each Gram Milliliter s.) Height 7.5"	Volume	Pieces 1 12
II. Generic Equivalent to What Brain II. Generic Equivalent to What Brain II. Generic Equivalent to What Brain II. Generic Equivalent III. Generic Equivalen	nd?: tion of manufactur exclusive distribun/exemption for pr n FDA.	DRUG SUPPLY rer? ttor? roduct?	Yes No No No No No AND HIBCC PRODUCT IN	DSCSA) INFOR	GLN: GCP: If yes, was o direct from n Provide sour	riginal product pur fr? cce manufacturer f	section fields are not applicable	(Write-in, e.g. 1 Write-in, e.g. 1 \text{ Write-in, e.g. 2 \text{ Write	Vial) Weight Lbs. 610.93gm dle/ 16.6 lbs 2364 lbs	AND PACKING IN Dimensis Depth 2.75*	Rx billing un NFORMATION Ons (US msm Width 2.06" 8.81" 35.63*	Each Gram Milliliter s.) Height 7.5"	Volume (Cube)	1 12 140
II. Generic Equivalent to What Brain II. Generic Equivalent to What Brain II. Generic Equivalent to What Brain II. Generic Equivalent III. Generic Equivalen	nd?: tion of manufactur exclusive distribun/exemption for pr n FDA.	DRUG SUPPLY rer? stor? coduct? GTIN caleable Quantity	Yes No No No No No AND HIBCC PRODUCT IN	DSCSA) INFOR	GLN: GCP: If yes, was o direct from n Provide sour	riginal product pur nfr? rce manufacturer fr IN-14 360846301151	section fields are not applicable	(Write-in, e.g. 1 Write-in, e.g. 1 \text{ Write-in, e.g. 2 \text{ Write	Customer? Vial) Weight Lbs. 610.93gm dle/ 16.6 lbs	AND PACKING IN Dimensis Depth 2.75*	Rx billing un NFORMATION Ons (US msm Width 2.06" 8.81" 35.63*	Each Gram Milliliter s.) Height 7.5"	Volume	1 12 140
II. Generic Equivalent to What Brain II. Generic Equivalent to What Brain II. Broduct exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Carton/Bundle/Inner Pack	nd?: tion of manufactur exclusive distribun/exemption for pr n FDA.	DRUG SUPPLY rer? ttor? roduct?	Yes No No No No No AND HIBCC PRODUCT IN	DSCSA) INFOR	GLN: GCP: If yes, was o direct from n Provide sour	riginal product pur fir? rce manufacturer f	section fields are not applicable	(Write-in, e.g. 1 Write-in, e.g. 1 \text{ Write-in, e.g. 2 \text{ Write	Vial) Weight Lbs. 610.93gm dle/ 16.6 lbs 2364 lbs	AND PACKING IN Dimensis Depth 2.75*	Rx billing un NFORMATION Ons (US msm Width 2.06" 8.81" 35.63*	Each Gram Milliliter s.) Height 7.5"	Volume (Cube)	1 12 140
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Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2021

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	SD	S 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	Contact Hazard				
		D 11 1 1 1 0 1					
c. Contact Hazard?	No	Does the product have an Aerosol class? If yes, identify NFPA Storage Level:					
 d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) 	No	NFPA Storage Level:					
e. Does the product contain DEHP?	No	NI FA Storage Level.					
		1 1 1 1 1 NICOLLI 1 1 1 0					
Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS)	No	Is the product a NIOSH hazardous drug? If yes, indicate which:	No				
a. UN/Identification Number		ii yes, ilidicate wilicii.					
b. Proper Shipping Name				<u>_</u>			
c. DOT Hazard Class			Hazardous Waste Identification				
d. Packing Group							
e. Inhalation Hazard?	No	EPA Hazardous Waste Code:	1	Waste Characteristics			
Is this product regulated for shipment by IATA?	No						
(if yes, answer a-e below and provide SDS)		REMS of	REGISTRY RESTRICTIONS				
a. UN/Identification Number							
b. Proper Shipping Name		Is there a REMS on this product?	No				
c. DOT Hazard Class d. Packing Group		If Yes, is it managed with a pharmacy registry? Website URL:					
e. Inhalation Hazard?	No	Website ORL.					
	140	Mad Cuida Bassisad		ı			
Is the product restricted for air shipment? If so, indicate restriction: Passenger		Med Guide Required Limited Distribution Requirement					
Cargo		Comments / Details: (For example, iPledge program?)					
Passenger & Cargo							
Is this a reportable quantity? No		REMS:	No				
RQ Threshold:		REMS Program Manager Name:	1.0	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 #:			
x Limited Quantity		Site Enrollment Number assigned		NCPDP#:			
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);		Continents					
SP#		Registry:	No				
3. <i>n</i>		Registry Program Contact Name:		Phone:			
ADD'L STORAGE INFORMATION		Comments					
Is the Product		1					
Controlled Substance? No Controlled Substance Code			ETURN 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?:	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							
Restricted to retail pharmacy only:		Special regulations or returns assurements for this					
		Special regulations or returns requirements for this product in certain states?					
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)		If so, which states? Other requirements? Comments?					
Comments:		ii 30, willon states: Other requirements: Other lents!					
Comments.							
	MISCELLANEO	US NOTES and/or Image of Product Barcode:					



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

Version 2021

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:		Purchase order daily receipt cut off time by supplier
a. EDI		Cut off time:
b. Autofax	Fax Number:	
c. Fax	Fax Number:	Shipping lead time of PO: Hours Days
d. Phone only	Phone No.:	China arma day faranya day manistr
e. Supplier Web Site only Minimum Order Quantity:	Site Address:	Ships same day for next day receipt: Ships for second day receipt:
Supplier's Customer Service Number:		Ships regular ground for 3-10 days receipt:
Contracted 3PL company / contact #:	Name:	Chips regular ground for a ready recorpt.
, , , , , , , , , , , , , , , , , , ,	Phone:	
Expedited Freight Cha	arges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order	er:	Overnight receipt available:
Drop Ship service fee billed with each orde	er:	PO Receipt cut off time:
Drop Ship miscellaneous fees billed:		Days of week overnight is available: Monday
Comments:		Tuesday
		Wednesday
		Thursday
		Friday
		Priority Overnight receipt available:
Cla	ss of Trade Restriction:	PO Receipt Cut off time:
No restriction: Select YES if sold to retail p	harmacy, hospitals, clinics and physician offices	Saturday Overnight receipt available:
Restricted to retail pharmacy only:	,	PO Receipt Cut off time:
Restricted to hospital, clinics, and physicial	n offices only:	Order receipt method: Phone: Phone #:
Restricted from US territories? (explain in o	comments)	Fax: Fax #:
Comments:		EDI:
		Overnight Fees apply:
		Other fees apply:
	formation Required to Process PO:	Return Instructions
Patient Procedure Date:		Contact # if product is received damaged:
Physician Name:		Is product returnable for credit:
Physician/Clinic Phone # Physician State License #		URL/Link to returns policy:
Physician/Clinic DEA #:		Special regulations or returns requirements for this product in certain states?
Physician/Clinic Specialty:		If so, which states? Other requirements? Comments?
, ,	Viscellaneous Notes:	
		ADDITIONAL INFORMATION
		Is product order for scheduled patient procedure?
		Is product order for restocking purposes?