

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

						Introduction Typ	pe: New Item		Final Version			Date:		2024
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	AGE REQUIF	REMENTS*		
Company Name:	Xiromed LLC					Applicatio	n: ANDA	a Temperatu	ure - Indicate the USP tempe	rature range for the	nis product			
Application Number for NDA/AN	-	MA/510(k)(med device	6).	2183	326			- La romporata	Temperature Range	Controlled Room -	- between 20	and 25 C (68	' – 77° F)	
Medical Device Class, if applicat		ro ro (n)(moa ao rio	• 7.						romporataro rtango					
DUNS:	790387927								Other Temperature Range F	Pequirement	None			
Proprietary Name (If Applicable) a		me GUAN	FACINE TABLETS, USP						(write in)	toquirerrierit	TTORIC			
Selling Unit NDC:	70700-301-01	anic.	Unit of Use NDC:			UPC: 3	370700301012	-	Notes					
UDI			CVX Code:			MVX Code:			110.00					
Description:	1 mg: white, oval,	flat-faced, beveled-e	dge tablet with "XI" on one s	side and "130" on	other side.				Is this product to be shipped				No	
A address to some all a made a la		GUANFACINE Tabl	-t- HOD					_	Is this product to be shipped	to customers on d	ry ice?		No	
Active Ingredient(s):		GUANFACINE TADI	ats USP					h Comtont for	r temperature excursion que					
URL for Additional Product Inform	antion:							D. Contact for	Name:	stions.	Vipul Gandhi			
Address:	180 Park Avenuu	Δ				Address 2:			Number:		862-895-623			
City:	Florham Park	•			State:		Zip : 07932	_	Group E-mail:				xiromed.co	nm .
Key Contact:	David Hernandez				Email:	usregulatory@xi		_	5.5up 2a		OS Quality	Allomede	All Officu.co	<u> </u>
Phone Number:	(845) 649-7130				Fax:	862-286-0932	- Concustoni	c. Special rec	gulations for product in any	states?			No	
Product Therapeutic Classification		Attention Deficit Hyr	peractivity Disorder (ADHD)	hypertension					Special returns requirement				No	
Troduct Therapeutic Glassification		/ Mondon Bonok 1191	ordouvity Bioordor (vibrib)	, riyportonolori					opeoiai retamo requirement	o for this product:			110	
	ADDITI	ONAL PRODUCT IN	ORMATION			PRODUCT DE	SCRIPTION INFORMATION	d Store prod	luct (unit of sale) upright?				Yes	
				Discret Ohio O				u. otore prou						
The product is?			Is the Product	Direct-Ship Or	niy			1	Protect product (unit of sa	le) from light?			No	
a legend device? if yes, enter class #		No	Is the Product Orphan Drug Status	Neither		Size:	11mm	e. Shelf life:	Initial shelf life at launch (£ -11.66 4) -			24	Months Months
a product kit?		No	Orphan Drug Status				1		initial shell life at launch (r amerent):			24	Wonths
if yes, list NDCs of		INU	FDA Approval Status			Strength:	1 mg			ORDER INFORM	ATION			
component parts			FDA Approvai Status				Tablets			ORBER IN OR	ATION			
reverse numbered?		No				Dosage Form:	Tablets		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present					'	X Bottle		1 Bottle cont			
latex-free?		Yes	_				Oval	1	Box/Carton		(Write-in, e.e.			
preservative-free?		Yes		No		Product Shape	9:		Ampule		. , ,		,	
correctional institution block?		Yes				Downstood Octoor	white		Glass		Minimum or	der quantity	?	Yes
opioid?		No				Product Color:			Tube				L	
Cannabinoid?		No	Country of Origin	India		Due divet les min	"XI" on one side and		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for		, ,			Product Imprir	"130" on other side		Vial Liquid Multi		If Yes, how	many of which	ch package ty	ype?
hospital scanning?		No	Is this product covered u	under the				1	Vial Powder Sql		24	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (TAA)?	No				Vial Power Multi			Inner/Carton	Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PR	RODUCTS							1			
											4			
					Au	thorized Generic *	If Authorized Generic, other		PH	ARMACY ORDER	/ RILL LINIT			
					710			Poc coll unit			/ DILL UNIT			
I. Orange Book Rating:	AB				7.00		section fields are not applicable	itec. sen unit	t to customer?		Rx billing ur	it to pharma	cy:	
I. Orange Book Rating: II. Generic Equivalent to What Bra		TENEX			7100		section fields are not applicable		t to customer? ottle with 100 Tablets			nit to pharma Each	ncy:	
							section fields are not applicable		ottle with 100 Tablets		Rx billing ur	Each Gram	ncy:	
			Y CHAIN SECURITY ACT	(DSCSA) INFORM			section fields are not applicable	1 Bo	ottle with 100 Tablets		Rx billing ur	Each	icy:	
II. Generic Equivalent to What Bra	nd?:	DRUG SUPPL		_	MATION	s	section fields are not applicable	1 Bo	ottle with 100 Tablets , 1 Vial)		Rx billing ur	Each Gram Milliliter	icy:	
II. Generic Equivalent to What Bra	nd?:	DRUG SUPPL	Yes	_			ection fields are not applicable	1 Bo	ottle with 100 Tablets , 1 Vial)	AND PACKING IN	Rx billing ur	Each Gram Milliliter	icy:	
II. Generic Equivalent to What Bra Does supplier meet DSCSA defini Is product exempt from DSCSA?	nd?:	DRUG SUPPL			MATION GLN:	s	ection fields are not applicable	1 Bo	ottle with 100 Tablets , 1 Vial)		Rx billing ur X	Each Gram Milliliter		
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II. Generic Equivalent to What Bra Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	nd?:	DRUG SUPPL	Yes No		MATION GLN: GCP:	00370700000007		1 Bo (Write-in, e.g.	ottle with 100 Tablets , 1 Vial)		Rx billing ur X	Each Gram Milliliter		Saleable # Pieces
II. Generic Equivalent to What Bra Does supplier meet DSCSA definition by the service of the supplier meet DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	nd?: tion of manufactu	DRUG SUPPL	Yes No		MATION GLN: GCP: If yes, was or	00370700000007		1 Bo	ottle with 100 Tablets . 1 Vial) ITEN	Dimensi	Rx billing ur X IFORMATION ons (US msm	Each Gram Milliliter	Volume	
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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 HAZARD CLASSIFICATION and TRANSPORTATION Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant?

a. Cytotoxic? 218326 No	SDS Hazard Classification
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	
Is the product a CA Prop 65 carcinogen?	Organic Corrosive
Is the product a CA Prop 65 reproductive toxicant?	Inorganic Oxidizer
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard
•	
c. Contact Hazard?	Does the product have an Aerosol class? If yes,
d. Does this product require special clean-up instructions?	identify NFPA Storage Level:
(If yes, attach SDS with special instructions.)	NFPA Storage Level:
e. Does the product contain DEHP?	
Is this product regulated for shipment by DOT?	Is the product a NIOSH hazardous drug? No
(if yes, answer a-e below and provide SDS)	If yes, indicate which:
a. UN/Identification Number	
b. Proper Shipping Name	
c. DOT Hazard Class	Hazardous Waste Identification
d. Packing Group	
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics
Is this product regulated for shipment by IATA?	
(if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS
a. UN/Identification Number	
b. Proper Shipping Name	Is there a REMS on this product?
c. DOT Hazard Class	If Yes, is it managed with a pharmacy registry?
d. Packing Group	Website URL:
e. Inhalation Hazard?	
Is the product restricted for air shipment? If so, indicate restriction:	Med Guide Required
Passenger	Limited Distribution Requirement
Cargo	Comments / Details: (For example, iPledge program?)
Passenger & Cargo	
Is this a reportable quantity? No	REMS:
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 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);	Comments
SP#	Registry:
3F#	Registry Program Contact Name: Phone:
ADD'L STORAGE INFORMATION	Comments
	Commons
Is the Product	DETURN INSTRUCTIONS
Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) No	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:
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	
Restricted to retail pharmacy only:	Special regulations or returns requirements for this
Restricted to hospital, clinics, and physician offices only:	product in certain states?
Restricted from US territories? (explain in comments)	If so, which states? Other requirements? Comments?
Comments:	
NIGOSI I AUS	NA VATEO - No long of Double December 1
MISCELLANEC	OUS 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: a. EDI b. Autofax Fax Number:	Purchase order daily receipt cut off time by supplier Cut off time:
c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Fax Number: Site Address: Site Address: Name:	Shipping lead time of PO: Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:
Phone:	
Expedited Freight Charges or Other Designated Drop Ship Fees: Expedited freight fees billed with each order:	Overnight and Priority Overnight PO Processing 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
	Priority Overnight receipt available:
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: 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: Miscellaneous Notes:	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?
	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure? Is product order for restocking purposes?