

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

						Introduction Typ	e: Post Launch Change		Final Version			Date:	7/10/2	
			PRODUCT INFORMA	ATION					SPECIAL HAN	DLING AND STOR	AGE REQUIF	EMENTS*		
Company Name:	Xiromed LLC					Application	ı: ANDA	a Temperatu	re - Indicate the USP tempe	rature range for the	nis product			
Application Number for NDA/AN		MA/510(k)(med devic	e):	218	326	Терентин		a. romporata	Temperature Range	Controlled Room -	- between 20	and 25 C (68	° – 77° F)	
Medical Device Class, if applica		iii a a a a a a a a a a a a a a a a a a	~ _/ .	1=14.					romporataro riango			(
DUNS:	790387927								Other Temperature Range F	Pequirement	None			
Proprietary Name (If Applicable) a		ame: GUAN	FACINE TABLETS, USP					1	(write in)	toquirerrierit	TTORIC			
Selling Unit NDC:	70700-302-01		Unit of Use NDC:	:		UPC: 3	70700302019		Notes					
UDI			CVX Code:			MVX Code:			110100					
											_			1
Description:	2 mg: white, oval,	flat-faced, beveled-ed	dge tablet with "XI" on one	side and "131" on	other side.				Is this product to be shipped				No	
A street to over the state.		OLIANIEA OINIE T-LI	- 4- LIOD					-	Is this product to be shipped	to customers on d	ry ice?		No	
Active Ingredient(s):		GUANFACINE Table	ets USP					h Control for	r temperature excursion que					
URL for Additional Product Inform	mation:							b. Contact for	Name:	estions:	Xiromed Qua	lity		
Address:	180 Park Avenuu	i e				Address 2:		-	Number:		862-895-623			
City:	Florham Park	-			State:		Zip: 07932	-	Group E-mail:				xiromed.co	om
Key Contact:	Xiromed Regulate	orv			Email:	usregulatory@xii		-	Group E-mail.		OS Quanty	Allonicue	XII OIIICU.CC	<u>OIII</u>
Phone Number:	(845) 649-7130	.,			Fax:	862-286-0932	<u>omed.com</u>	c. Special red	julations for product in any	states?			No	1
Product Therapeutic Classification		Attention Deficit Hyr	peractivity Disorder (ADHD)) hypertension					Special returns requirement				No	
1 Todact Therapeatic Glassification	JII.	/ tabilabil Bolloit 11)p	oradavity Biodradi (18118)	y, rryportonoron					opedia returns requirement	o for this product:			140	J
	ADDIT	IONAL PRODUCT INF	ORMATION			PRODUCT DE	SCRIPTION INFORMATION	d Store prod	uct (unit of sale) upright?				Yes	1
				Discret Ohio O	. h.			u. otore prou]
The product is?			Is the Product	Direct-Ship Or	niy				Protect product (unit of sa	le) from light?			No	
a legend device?		No	Is the Product	Neither		Size:	11mm	e. Shelf life:	In Wallahald IV. at law ab C	£ -11.66 4) -			24	Months
if yes, enter class # a product kit?		No	Orphan Drug Status				2 MG		Initial shelf life at launch (i	r airrerent):			24	Months
if yes, list NDCs of		INO	FDA Approval Status			Strength:	2 IVIG			ORDER INFORM	ATION			
component parts			FDA Approvai Status				Tablets			ORDER IN ORI	ATION			
reverse numbered?		No				Dosage Form:	lablets		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						X Bottle		1 Bottle cont			
latex-free?		Yes					Oval		Box/Carton		(Write-in, e.e.			
preservative-free?		Yes		No		Product Shape			Ampule		(,	, , , , ,	
correctional institution block?		Yes					white		Glass		Minimum or	der quantity	?	Yes
opioid?		No				Product Color:			Tube					
Cannabinoid?		No	Country of Origin	India			"XI" on one side and		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for		, , ,			Product Imprin	"131" on other side		Vial Liquid Multi		If Yes, how	nany of whi	ch package t	type?
hospital scanning?		No	Is this product covered	under the					Vial Powder Sql			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act ((TAA)?	Yes				Vial Power Multi			Inner/Carton	/Pack	
			_	-					Other: Write In			Case		
			FOR GENERIC DRUG PF	RODUCTS										
			FOR GENERIC DRUG PF	RODUCTS										
			FOR GENERIC DRUG PR	RODUCTS	Au		f Authorized Generic, other		PH	ARMACY ORDER				
I. Orange Book Rating:	AB		FOR GENERIC DRUG PR	RODUCTS	Au		f Authorized Generic, other ection fields are not applicable	Rec. sell unit	PH to customer?	ARMACY ORDER	/ BILL UNIT	it to pharma	cy:	
I. Orange Book Rating: II. Generic Equivalent to What Bra		TENEX	FOR GENERIC DRUG PR	RODUCTS	Au					ARMACY ORDER		i it to pharma Each	ıcy:	
				[to customer? tles with 100 Tablets	ARMACY ORDER	/ BILL UNIT		ncy:	
			FOR GENERIC DRUG PR	[1 Bot	to customer? tles with 100 Tablets	ARMACY ORDER	/ BILL UNIT Rx billing ur	Each	ıcy:	
II. Generic Equivalent to What Bra	and?:	DRUG SUPPL'	Y CHAIN SECURITY ACT	(DSCSA) INFORI	MATION	SI		1 Bot	to customer? tles with 100 Tablets 1 Vial)		/ BILL UNIT Rx billing ur X X	Each Gram Milliliter	icy:	
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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: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro	and?: s exclusive distribone/exemption for pom FDA.	DRUG SUPPL	Y CHAIN SECURITY ACT Yes No No No No No No AND NO	(DSCSA) INFORI	MATION GLN: GCP: If yes, was ordirect from mean provide sour	00370700000007 riginal product purchaft? cce manufacturer for re	ection fields are not applicable	Item/Each: Box/Carton/Binner Pack:	to customer? tles with 100 Tablets 1 Vial) Weight Lbs. 0.12	AND PACKING IN Dimension Depth 1.913	/ BILL UNIT Rx billing ur X X IFORMATION Ons (US msm Width 1.52	Each Gram Milliliter tts.) Height 2.694	Volume (Cube) 7.8335054	Pieces 1
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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 H	IAZARD CLASSIFICATION and TRANSPORTATION
Is this product (check all that apply):	
a. Cytotoxic?	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? Does the product label bear a CA Prop 65 warning? No	Inorganic Oxidizer Steroid/Androgen Contact Hazard
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	NAZATUVUS WASIE IUEIKIILAKUVII
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 Cargo	Limited Distribution Requirement Comments / Details: (For example, iPledge program?)
Passenger & Cargo	Confinents / Details. (For example, irredge program?)
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 Small Quantity (49 CFR 173.4)	by Supplier: NPI #:
Special Permit; DOT-SP	Comments
Special Provision (listed in Column 7 of 49 CFR 172.101);	Committee
SP#	Registry:
	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:
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:	
MISCELLAN	IEOUS NOTES and/or Image of Product Barcode:
WISCELLAN	12000 NOTES and of Find duct Balcode.



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?