

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

Version 2021						Introduction Type:	New Item		x Final Version			Date:	9/9/2	2022
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	AGE REQUI	REMENTS*		
Company Name:	TAGI Pharma, Inc					Application:	ANDA	a. Temperatu	re - Indicate the USP tempe	rature range for the	nis product.			
Application Number for NDA/AN	IDA/BLA (drug); PN	A/510(k)(med device	ce):	212875			<u> </u>			Controlled Room -		and 25 C (68	3° – 77° F)	
Medical Device Class, if applicable:														
DUNS:	963322560								Other Temperature Range R	equirement				
Proprietary Name (If Applicable)	and Established Na	me: Chlort	halidone Tablets, USP					I	(write in)					
Selling Unit NDC:	51224-118-50		Unit of Use NDC:			UPC:		I	Notes					
UDI			CVX Code:			MVX Code:		1						
Description:	Chlorthalidone Ta	blets USP, 50mg 100	Oct					T	Is this product to be shipped	to customers on ic	ce?		No	
·		. •							Is this product to be shipped	to customers on d	ry ice?		No	
Active Ingredient(s):		Chlorthalidone						1						
								b. Contact fo	r temperature excursion que	stions:				
URL for Additional Product Inform		www.tagipharm	a.com_						Name:					
Address:	722 Progressive L	n Room 205			.	Address 2:	1	-	Number:		815-624-768			
City:	South Beloit Drake Sundstrom				State: Email:		o: 61080	-	Group E-mail:		druginto@	tagipharm	a.com	
Key Contact: Phone Number:	815-624-7685				Fax:	dsundstrom@tagip 815-624-4628	narma.com_	a Special rea	gulations for product in any	totoo?			No	1
Product Therapeutic Classification					ı ax.	013-024-4020		c. Special reg	Special returns requirements				No	
Product Therapeutic Classification	on:								Special returns requirement	s for this product?			INO	I
	ADDITIO	ONAL PRODUCT IN	FORMATION			PRODUCT DESC	CRIPTION INFORMATION	d Store prod	uct (unit of sale) upright?				Yes	1
	ADDITIO	SNALT RODUCT IN		Discoul And David On		TRODUCT DESC	INIT HON IN CRIMATION	u. Store prod						1
The product is?			Is the Product	Direct And Drop-Sh Neither	nip		100		Protect product (unit of sa	e) from light?			Yes	
a legend device?		No	Is the Product Orphan Drug Status	Neither		Size:	100	e. Shelf life:	halfal ab alf life at lass ab fi				24	Months
if yes, enter class # a product kit?			Orphan Drug Status				50mg		Initial shelf life at launch (i	amerent):				Months
if yes, list NDCs of			FDA Approval Status			Strength:	Somg			ORDER INFORM	IATION			
component parts			. Dririppioral Glatag				Tablet							
reverse numbered?		No				Dosage Form:			Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		Yes	Allergens Present						x Bottle		1 bottle of 1	00 tablets		
latex-free?		Yes				Product Shape:	Round		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		Yes				i roduct onape.			Ampule					
correctional institution block?		No				Product Color:	Pale Green		Glass		Minimum o	rder quantity	/?	Yes
opioid?		No							Tube					
Cannabinoid?		No	Country of Origin	Portugal		Product Imprint:	Scored tablet debossed with "TP" in top score and		Vial Liquid Sgl					
If Unit Dose, is item bar coded to hospital scanning?	unit dose for	No	la thia anadorat accessed .				"50" in bottom score and		Vial Liquid Multi			many of wh	ich package t	ype?
If Unit Dose, indicate NDC here:		NO	Is this product covered to Trade Agreements Act (plain on the other side		Vial Powder Sql Vial Power Multi		ь	Inner/Cartor	/Book	
Il Offit Dose, indicate NDC fiere.			Trade Agreements Act (inn): Tes					Other: Write In			Case	I/Fack	
			FOR GENERIC DRUG PR	ODUCTS				<u> </u>	Galer. Write in			Ousc		
			TOR GENERIC DROG FR	000013										
					Aut	thorized Generic *If A	Authorized Generic, other		PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB						tion fields are not applicable	Rec sell unit	to customer?		Rx billing u	nit to nharm	2011	
II. Generic Equivalent to What Bra		Chlorthalidone						Tee. sen uni	to customer i		KX billing u	Each	acy.	
ii. Generic Equivalent to What Bra	and:.	Oniorarandoric						(Write-in, e.g	. 1 Vial)			Gram		
		DRUG SUPPL	Y CHAIN SECURITY ACT	(DSCSA) INFORMAT	ION			(**************************************				Milliliter		
Does supplier meet DSCSA defin		er?	Yes	GLN	:	0351224000001			ITEM	AND PACKING IN	NFORMATIO	N		
Is product exempt from DSCSA?			No											
If yes, select exemption:				GCP) :				Maight I ha	Dimensi	ons (US msn	nts.)	Volume	Saleable #
Other exemption - Write in:									Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No			iginal product purchase	ed	Item/Each:	0.02	1.5	1.5	3.16	7.11	1
Is product sold by manufacturer's			No		ct from m									
Has FDA granted waiver/exception		oduct?	No	Prov	ride sourc	ce manufacturer for rep	ackaged product	Box/Carton/E	Sundle/					
If yes, attach documentation fro	m FDA.													
		GTI	N AND HIBCC PRODUCT I	NEODMATION				Case:	2.16	9.65	6.42	3.54	219.31362	24
		011	N AND HIDCOT RODOCT I	NIORMATION				Pallet:						
Saleable Unit of Measure	9	aleable Quantity	HIBCC		GTI	N-14	Unit of Use GTIN-14	III allet.						
X Item/Each	3	1	. 11500			51224118508	5111 61 636 GTH4-14							
Box/Carton/Bundle/Inner Pack					2300				COST INFORMATION			WHOLESAL	ER USE ONL	Y:
Case		24			5035	51224118503								
Pallet								Regular Cost	1		Vendor #:			
								Invoice Cost	(WAC) (\$)	\$21.90	Whsl. Code			
											Fineline Co	de:		
								As of date:	9/9/2022		Į			
 				T. OUEET (05 -:				LL			L			
		•	Aπach copy of SAFETY D	ATA SHEET (SDS) or	non hazai		ERT, LABEL AND PHOTO OF F anated Drop Ship Only.	PRODUCT PACK	AGING and BARCODE. Signature:			D1 0	undstrom	
*Please provide any additional in														



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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD 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?	Inorganic Oxidizer						
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard						
c. Contact Hazard? Yes	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.)	NFPA Storage Level:						
e. Does the product contain DEHP?	NFFA Stolage Level.						
·							
Is this product regulated for shipment by DOT?	Is the product a NIOSH hazardous drug?						
(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	Hazardous Wasie neminication						
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics						
	Transfer Transfer Control Cont						
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	REING OF REGISTRY RESTRICTIONS						
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 No						
Passenger	Limited Distribution Requirement						
Cargo	Comments / Details: (For example, iPledge program?)						
Passenger & Cargo	Commence, Establish, G. Shampio, I. 1889 programmy						
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);							
SP#	Registry:						
Chlorthalidone	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: 800-397-9228						
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:	product in certain states? Yes						
Restricted from US territories? (explain in comments)	If so, which states? Other requirements? Comments?						
Comments:	Georgia, Mississippi, and North Carolina. Requests can be made via fax: (815) 624-0608 or email customercare@tagipharma.com						
MISCELLAN	EOUS NOTES and/or Image of Product Barcode:						
- IIIIOCEEEAN							



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FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop S	nip Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI		Purchase order daily receipt cut off time by supplier Cut off time:
b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	per:	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 Designa	ed Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order:		Overnight receipt available: 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, clinic Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	s and physician offices	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to F	rocess PO:	Return Instructions
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:		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?