

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

Major Course Property Pro	Version 2021 Introduction Type: Post Launch Change										x Fir	nal Version			Date:	7/12/	2021	
Application Name for NAMADIANE A Page Page 1979	PRODUCT INFORMATION								SPECIAL HANDLING AND STORAGE REQUIREMENTS*									
Application Name for NAMADIANE A Page Page 1979											a Temperature – Indicate the USP temperature range for this product							
March Care Approach Care Ca				ce):	21	2218	7.ppou.		7.11571	u. remperatu					and 25 C (68	° – 77° F)		
March Marc			,,,												(
Popular Popu											Other Temp	erature Range R	equirement					
Montange	Proprietary Name (If Applicable) a	and Established N	ame: Clomir	pramine HCI Capsules								-	•					
Compare Comp							UPC:	3-5974	46-711-30-6									
Contact Cont	UDI			CVX Code:			MVX Code:											
Contact Cont	Description:	Clomipramine Hv	drochloride 50ma 30c	ct Capsules							Is this produ	ct to be shipped	to customers on in	ce?		No		
Control of Project O																		
Marchanistand Products Information Marchanistand Products Marchan	Active Ingredient(s):		Clomipramine Hydr	rochloride										-				
Add case System Fig. State Sta										b. Contact for	r temperature	excursion que	stions:					
Spring S			www.cadista.co	m/products/full-product	<u>t-list</u>					Name: Customer Service								
Email Special contents Special regulations for groduct in any states? Special regulation for groduct in any states? Special regulati																		
Pisse											Group E-mail:				customer.service@cadista.com			
ADDITIONAL PRODUCT INFORMATION PRODUCT BESCRIPTION INFORMATION PRODU			V						<u>ibl.com</u>	Special regulations for mandrest in any of the C						Nie		
## ADDITIONAL PRODUCT NO CREATION The product 137 The p			Antidonunanan			l ax.	(215) - 443 - 9646											
Production is 2 1	Product Inerapeutic Classification: Antioepressant Special returns requirements for this product? No																	
Production is 2 1		ADDITI	IONAL PRODUCT IN	FORMATION			PRODUCT	DESCRI	IPTION INFORMATION	d Store prod	uct (unit of e-	ala) unright?				No		
A special devices No. Size Special product Size Size Special product Size Size Special product Size	The area dept to C	ABDIII	IONAL I RODOCI IN		Direct Chi:	Only	TROBUCTE	3-00M	I HON IN ORMATION	a. Store prou	•		1-3 france P 1 1 6					
Section Sect						Jrily			20	a Chalf life.	Protect pro	duct (unit of sal	le) from light?				Mautha	
FOA Approval Status Strength: Streng	_		No		Nettriei		Size:		30 Count	e. Shell life:	Initial shalf	life at launch (it	different).			24		
Secretarian Mode of Consponent parts reverse numbered? No. Altergrane Present Product Color: White Constanting of Many Product Color: No. Constanting of Many Product Color:			No	Orphan Drug Status					50mg		IIIIIIai Sileii	ille at lauticii (ii	i dillerent).				WOILLIS	
Dosage Form: CAPSILLES Product Shape: Capsulos Shape: Ca						Strength:		Joing				ORDER INFORM	IATION	TION				
The first contribution of the first contribu							D F		CAPSULES									
Later-keracy Visc product Shapping Capsulo, Size 1 Product Color: White product Color: White Colors a flore back of the Color of the Co	reverse numbered?		No				Dosage Form	n:			Unit of Sale			What is the	NDC selling	unit?		
Product carea Product correctional station block? Vas opioid? No. Country of Origin US Product Color: Vision Vi	co-licensed?		No	Allergens Present							X Bo	ttle		1 bottle of 3	0 capsules			
Product Color: White Product Color: White Product Color: White Product Color: White Product Imprint: C7711 White			Yes				Product Sha	ipe:	Capsule, Size 1					(Write-in, e	.g. 1 Box of 1	0 Vials)		
poide? Cannabnid? If Unit Dose, is den bar coded to unit dose for Noglet Service Control Foods. It was a service of the Control Foods Agreements Act (TAA)? If Unit Dose, indicate NDC hats: FOR CENERIC GRIGG PRODUCTS Authorized Genetic, Other section fields are not applicable in Genetic Control Foods are not applicable in Genet																_		
Value Liquid Supply Foots Liquid Multiple Liquid Multipl							Product Cold	or:	White					Minimum o	rder quantity	?	Yes	
If Unit Dose, is dem bar coded to unit dose for hospital scanning? If Unit Dose, is dicate NDC here: Index Agreements Act (TAA)? Yes	·			Country of Origin	IIQ				C / 711									
Saleshie Country Saleshie Co		init dose for	NO	Country of Origin	03		Product Imp	rint:	6/711					If Yes how	many of whi	ch nackage	tvne?	
Trade Agreements Act (TAA)? Yes		ariit dose roi		Is this product covered u	nder the											on package	урс.	
Authorized Genetic "If Authorized Genetic glivalent to What Brand?" Authorized Genetic glivalent to What Brand?" Anafranial				Yes														
Authorized Genetic, Other section fields are not applicable section fiel															Case			
1. Crange Book Rating: AB				FOR GENERIC DRUG PRO	DDUCTS		•											
1. Crange Book Rating: AB																		
Continue						Au	uthorized Generic					PHA	ARMACY ORDER	/ BILL UNIT				
Continue	I. Orange Book Rating: AB						section	n fields are not applicable	Rec. sell unit to customer?				Rx billing unit to pharmacy:					
Cost	II. Generic Equivalent to What Brand?: Anafranil							1 bottle of 30 capsules				X Each						
Second continue of manufacturer Yes Substitution of manufacturer Yes Substitution of manufacturer Yes Substitution of manufacturer Yes Substitution Yes Substitution Yes Substitution Yes Substitution Yes Substitution Yes Yes Substitution Yes Yes Substitution Yes										(Write-in, e.g.	1 Vial)							
Seproduct exempt from DSCSA?			DRUG SUPPL	Y CHAIN SECURITY ACT (DSCSA) INFOF	RMATION									Milliliter			
Seproduct exempt from DSCSA?	Dogs supplier most DSCSA definit	ition of manufact.	ror?	Vac	7	GI N:	0350746000004					_ ITEM	AND PACKING IN	JEORMATIO	N			
Figure 1		nion oi manuractu	ii ei f		-	GLIV.	0339740000004					IIEM	AND TACKING II	W-OKWIATIO	N-			
Other exemption - Write in: Is product repackaged? Has FDA granted waiver/exception/exemption for product? If yes, attach documentation from FDA. Saleable Unit of Measure Saleable Unit of Use GTIN-14	•			110									D !	(110				
It yes, was original product packaged? No purchased direct from fff? Has FDA granted waiver/exception/lexemption for product? If yes, attach documentation from FDA. It wes fash 1						GCP:	0359746					Weight Lbs.			-			
Is product sold by manufacturer's exclusive distributor? Has FDA granted waiver/exception/exemption for product? If yes, attach documentation from FDA. Saleable Unit of Measure Saleable Quantity HIBCC GTIN-14 Unit of Use GTIN-14 SowCarton/Bundle/Inner Pack	•			No		If you was a	riginal product			Itom/Each:			Deptn	wiath	neight	(Cube)	rieces	
Has FDA granted waiver/exception/exemption for product? If yes, attach documentation from FDA. Saleable Unit of Measure Saleable Quantity HIBCC GTIN-14 Unit of Use GTIN-14 Saleable Unit of Measure Saleable Quantity HIBCC GTIN-14 Unit of Use GTIN-14 Unit of Use GTIN-14 GOST INFORMATION Pallet GOST INFORMATION WHOLESALER USE ONLY:		exclusive distrib	utor?		-					itemy Eduli.		0.08	1.8	1.8	3	9.72	1	
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Saleable Unit of Measure Saleable Unit of Measure Saleable Quantity HIBCC GTIN-14 Unit of Use GTIN-14 COST INFORMATION WHOLESALER USE ONLY: Regular Cost Invoice Cost (WAC) (\$) \$145.74 Whish. Code #: Fineline Code: As of date:										Case:		2.42	11	7.5	4.25	350.63	24	
Saleable Unit of Measure Saleable Quantity HIBCC GTIN-14 Unit of Use GTIN-14			GTII	N AND HIBCC PRODUCT IN	IFORMATION							2.42		7.5	4.23	330.03	24	
Saleable Unit of Measure Saleable Quantity HIBCC GTIN-14 Unit of Use GTIN-14										Pallet:						0.00		
Bow/Carton/Bundle/Inner Pack X Case Pallet Invoice Cost (WAC) (\$) S145.74 Whist. Code #: Fineline Code: Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.		\$		HIBCC					Unit of Use GTIN-14									
X Case 24 40359746711304 Regular Cost Vendor #:			1			003	559/46/11306			COST INFORMATION MHOLES ALER LISE ONLY								
Pallet Regular Cost Vendor #:			24			402	59746711304				COST IN	II-OKWATION			WHOLESAL	LK USE UNL	1.	
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Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.											· · · - / (* /		ψ1-0.74					
										As of date:								
	*Places provide and additional land	iormation	. 2	Attach copy of SAFETY DA	TA SHEET (SD	S) or non haza					AGING and B	ARCODE.						



Version 2021

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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? No SDS Hazard Classification b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Nο Organic Corrosive Is the product a CA Prop 65 reproductive toxicant? No Inorganic Oxidizer Does the product label bear a CA Prop 65 warning? Steroid/Androgen Contact Hazard No 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? No (If yes, attach SDS with special instructions.) NFPA Storage Level: e. Does the product contain DEHP? No Is this product regulated for shipment by DOT? No 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 **Hazardous Waste Identification** c. DOT Hazard Class d. Packing Group EPA Hazardous Waste Code: Waste Characteristics e. Inhalation Hazard? No Is this product regulated for shipment by IATA? No (if yes, answer a-e below and provide SDS) REMS or REGISTRY RESTRICTIONS a. UN/Identification Number Is there a REMS on this product? b. Proper Shipping Name c. DOT Hazard Class If Yes, is it managed with a pharmacy registry? d. Packing Group Website URL: e. Inhalation Hazard? No Is the product restricted for air shipment? If so, indicate restriction: No Med Guide Required No Passenger Limited Distribution Requirement No Cargo Comments / Details: (For example, iPledge program?) Passenger & Cargo Is this a reportable quantity? REMS: RQ Threshold: REMS Program Manager Name: Phone Is this a marine pollutant? Nο Supplier Manages REMS registry exclusively: Is this product shipped utilizing an authorized DOT exception or Special Permit? Wholesale distributor support: (if yes, identify method below) Provider Name: DEA #: Site Enrollment Number assigned NCPDP# Limited Quantity Consumer Commodity, ORM-D NPI#: by Supplier: Small Quantity (49 CFR 173.4) Special Permit: DOT-SP Comments Special Provision (listed in Column 7 of 49 CFR 172.101); SP# Registry: Phone: Registry Program Contact Name: ADD'L STORAGE INFORMATION Comments Is the Product RETURN INSTRUCTIONS Controlled Substance? No Controlled Substance Code 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 Yes Restricted to retail pharmacy only: 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: MISCELLANEOUS NOTES and/or Image of Product Barcode



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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 c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	Purchase order daily receipt cut off time by supplier Cut off time: 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 Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing							
Expedited freight fees billed with each order:	Overnight receipt available:							
Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	PO Receipt cut off time: 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?							