

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

Version 2020					l.	Introduction Type:	New Item		x Final Version			Date:	10/26	/2022	
	SPECIAL HANDLING AND STORAGE REQUIREMENTS*														
Company Name:	a. Temperature – Indicate the USP temperature range for this product.														
Application Number for NDA/AN			Agent for Cadila Pharmaceutic vice):	212645	ANDA	Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)									
DUNS:	858949204					Other Temperature Range Requirement									
Proprietary Name (If Applicable) a		Parox	ketine Extended-Release Tablet	ts 12 5mg					(write in)	Requirement					
Selling Unit NDC:	72241-029-22	ie. 1 0.05	Unit of Use NDC:	io izionig		UPC: 37224 <sup>2</sup>	1029226	No							
UDI			CVX Code:		N	MVX Code:									
Description:	Parovetine Extende	d-Release Tablet	s 12 5mg 30s					le t	his product to be shipped	d to customers on i	ce2		No		
Description: Paroxetine Extended-Release Tablets 12.5mg 30s									Is this product to be shipped to customers on ice? No Is this product to be shipped to customers on dry ice? No						
Active Ingredient(s):	131	This product to be shipped		ary ice:		INU									
Active Ingredient(s): Paroxetine 12.5mg									b. Contact for temperature excursion questions:						
URL for Additional Product Information: www.modavar.com							Name: Customer Service								
Address:	1016 16th St., NW,	Suite 602			Addr	ress 2:		Number:			800-688-4697				
City:	Washington			Group E-mail: ModavarCS@Eversana.com											
Key Contact:	Lewis "Lewis "Soars         Email:         Lewis@Modavar.com           (202) 868-2391         Fax:         (202)355-9784														
Phone Number:	(202) 868-2391	Antidepressant		c. Special regulations for product in any states? No											
Product Therapeutic Classification	Special returns requirements for this product? No														
ADDITIONAL PRODUCT INFORMATION PRODUCT DESCRIPTION INFORMATION									d. Store product (unit of sale) upright? No						
The product is?									Protect product (unit of sale) from light? No						
a legend device?	I	No	Is the Product	Neither	30 ct bottle	e. Shelf life: 24 Months									
if yes, enter class #		Na	Orphan Drug Status	Init	ial shelf life at launch (	lit different):				Months					
a product kit? if yes, list NDCs of	· · · · · · · · · · · · · · · · · · ·	No	FDA Approval Status			ORDER INFORM	NATION								
component parts			T DA Approval Status				Tablet								
reverse numbered?		No			-	Dosage Form:		Un	it of Sale		What is the	NDC selling	unit?		
co-licensed?		No	Allergens Present						X Bottle		1 bottle of 3	0 tablets			
latex-free?	,	Yes	See Package Insert -	nationt specific		Product Shape:	Round, biconvex		Box/Carton		(Write-in, e	g. 1 Box of 1	) Vials)		
preservative-free?		Yes	Gee Fackage insert	patient specific		riouuci onape.			Ampule						
correctional institution block?	-	No				Product Color:	yellow		Glass		Minimum o	rder quantity	?	Yes	
opioid?	-	No							Tube						
Cannabinoid?	-	No	Country of Origin	India		Product Imprint:	debossed 'X1' one side; plain on other		Vial Liquid Sgl		W M				
If Unit Dose, is item bar coded to u scanning?	nit dose for nospital		Is this product covered und	der the			plain on other		Vial Liquid Multi Vial Powder Sql		24	Each	ch package t	yper	
If Unit Dose, indicate NDC here: Trade Agreements Act (TAA)? No						Vial Power Multi				24 Each Inner/Carton/Pack					
									Other: Write In Case						
FOR GENERIC DRUG PRODUCTS															
Authorized Generic *If Authorized Generic, other section								PHARMACY ORDER / BILL UNIT							
I. Orange Book Rating: AB fields are not applicable								Rec. sell unit to customer? Rx billing unit to pharmacy:							
II. Generic Equivalent to What Brand?: Paxil® CR								1 pill <b>x</b> Each							
									(Write-in, e.g. 1 Vial) Gram						
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION												Milliliter			
Does supplier meet DSCSA definition of manufacturer? Yes GLN: 372241000003									ITEN			M			
Does supplier meet DSCSA definit Is product exempt from DSCSA?	tion of manufacture		Yes	GLN:	312	2241000003		ITEM AND PACKING INFORMATION							
	-		110	-				1		Dimensi		- 1 - 1			
If yes, select exemption:	-						_		Weight Lbs.		ions (US msn		Volume (Cube)	# Pieces:	
Other exemption - Write in: Is product repackaged?	L		No	If Yes wa	as original p	roduct purchased	_	Item/Each:		Depth	Width	Height			
Is product sold by manufacturer's	exclusive distribut	or?	No	direct fro		founder purchased		nem/Lach.	0.0683	2.9528	2.9528	1.5748	13.730725	1	
Has FDA granted waiver/exception			No			entation from FDA.		Box/Carton/Bund	le/	4.04400000-	4.04.1007.5	0.00000./=	7 747574	0.1	
3				_				Inner Pack:	2.36	1.811023622	1.8110236	2.3622047	7.7475744	24	
		GT	IN AND HIBCC PRODUCT INF	ORMATION				Case:	13.21	16.14173228	12.598425	9.8425197	2001.5788	96	
									13.21	16.14173226	12.596425	9.0425197	2001.5766	90	
Saleable Unit of Measure	<u>(</u>	Quantity	HIBCC		GTIN-14		Unit of Use GTIN-14	Pallet:	442.7312775	47.24409449	39.370079	45.669291	84945.052	3456	
X Item/Each	L	1				41029226									
X         Case         96         40372241029224           X         Pallet         3456         50372241029221								COST INFORMATION WHOLESALER USE ONLY:							
	ŋ ŀ	3430			3031222			Regular Cost			Vendor #:				
	1 1							Invoice Cost (WA	C) (\$)	\$12.44	Whsl. Code	#:			
	1 1										Fineline Co				
	1 1							As of date:	10/26/2022						
Ш															
			Attach copy of SAFETY DAT	A SHEET (SDS) or n	non hazard let	tter, PACKAGE INSE	RT, LABEL AND PHOTO OF	PRODUCT PACKAGI	NG and BARCODE.						
*Please provide any additional infe	ormation on page 2				See	e new p. 3 for Desig	nated Drop Ship Only.	Sig	nature:						