



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

Version 2020		Introduction Type: <span style="border: 1px solid black; padding: 2px;">New Item</span>		<input checked="" type="checkbox"/> Final Version		Date: <span style="border: 1px solid black; padding: 2px;">10/26/2022</span>	
PRODUCT INFORMATION							
Company Name:		<span style="border: 1px solid black; padding: 2px;">Modavar Pharmaceuticals LLC (U.S. Agent for Cadila Pharmaceuticals Limited)</span>		Application:		<span style="border: 1px solid black; padding: 2px;">ANDA</span>	
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):		<span style="border: 1px solid black; padding: 2px;">212645</span>					
DUNS:		<span style="border: 1px solid black; padding: 2px;">858949204</span>					
Proprietary Name (If Applicable) and Established Name:		<span style="border: 1px solid black; padding: 2px;">Paroxetine Extended-Release Tablets 12.5mg</span>					
Selling Unit NDC:		<span style="border: 1px solid black; padding: 2px;">72241-029-22</span>		Unit of Use NDC:		<span style="border: 1px solid black; padding: 2px;">372241029226</span>	
UDI		<span style="border: 1px solid black; padding: 2px;"></span>		CVX Code:		<span style="border: 1px solid black; padding: 2px;"></span>	
Description:		<span style="border: 1px solid black; padding: 2px;">Paroxetine Extended-Release Tablets 12.5mg 30s</span>					
Active Ingredient(s):		<span style="border: 1px solid black; padding: 2px;">Paroxetine 12.5mg</span>					
URL for Additional Product Information:		<span style="border: 1px solid black; padding: 2px;"><a href="http://www.modavar.com">www.modavar.com</a></span>					
Address:		<span style="border: 1px solid black; padding: 2px;">1016 16th St., NW, Suite 602</span>		Address 2:		<span style="border: 1px solid black; padding: 2px;"></span>	
City:		<span style="border: 1px solid black; padding: 2px;">Washington</span>		State:		<span style="border: 1px solid black; padding: 2px;">DC</span>	
Key Contact:		<span style="border: 1px solid black; padding: 2px;">Lewis "Lew" Soars</span>		Zip:		<span style="border: 1px solid black; padding: 2px;">20036</span>	
Phone Number:		<span style="border: 1px solid black; padding: 2px;">(202) 868-2391</span>		Email:		<span style="border: 1px solid black; padding: 2px;"><a href="mailto:Lewis@Modavar.com">Lewis@Modavar.com</a></span>	
Product Therapeutic Classification:		<span style="border: 1px solid black; padding: 2px;">Antidepressant</span>		Fax:		<span style="border: 1px solid black; padding: 2px;">(202)355-9784</span>	
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
The product is?		<span style="border: 1px solid black; padding: 2px;">No</span>		Is the Product... Direct And Drop-Ship		<span style="border: 1px solid black; padding: 2px;">Neither</span>	
a legend device?		<span style="border: 1px solid black; padding: 2px;"></span>		Is the Product... Orphan Drug Status		<span style="border: 1px solid black; padding: 2px;"></span>	
if yes, enter class #		<span style="border: 1px solid black; padding: 2px;"></span>		FDA Approval Status		<span style="border: 1px solid black; padding: 2px;"></span>	
a product kit?		<span style="border: 1px solid black; padding: 2px;">No</span>		Allergens Present		<span style="border: 1px solid black; padding: 2px;">See Package Insert - patient specific</span>	
if yes, list NDCs of component parts		<span style="border: 1px solid black; padding: 2px;"></span>		Country of Origin		<span style="border: 1px solid black; padding: 2px;">India</span>	
reverse numbered?		<span style="border: 1px solid black; padding: 2px;">No</span>		Is this product covered under the Trade Agreements Act (TAA)?		<span style="border: 1px solid black; padding: 2px;">No</span>	
co-licensed?		<span style="border: 1px solid black; padding: 2px;">No</span>		Size:		<span style="border: 1px solid black; padding: 2px;">30 ct bottle</span>	
latex-free?		<span style="border: 1px solid black; padding: 2px;">Yes</span>		Strength:		<span style="border: 1px solid black; padding: 2px;">12.5mg</span>	
preservative-free?		<span style="border: 1px solid black; padding: 2px;">Yes</span>		Dosage Form:		<span style="border: 1px solid black; padding: 2px;">Tablet</span>	
correctional institution block?		<span style="border: 1px solid black; padding: 2px;">No</span>		Product Shape:		<span style="border: 1px solid black; padding: 2px;">Round, biconvex</span>	
opioid?		<span style="border: 1px solid black; padding: 2px;">No</span>		Product Color:		<span style="border: 1px solid black; padding: 2px;">yellow</span>	
Cannabinoid?		<span style="border: 1px solid black; padding: 2px;">No</span>		Product Imprint:		<span style="border: 1px solid black; padding: 2px;">debossed "X1" one side; plain on other</span>	
If Unit Dose, is item bar coded to unit dose for hospital scanning?		<span style="border: 1px solid black; padding: 2px;"></span>					
If Unit Dose, indicate NDC here:		<span style="border: 1px solid black; padding: 2px;"></span>					
FOR GENERIC DRUG PRODUCTS							
I. Orange Book Rating:		<span style="border: 1px solid black; padding: 2px;">AB</span>		Authorized Generic		<input type="checkbox"/> If Authorized Generic, other section fields are not applicable	
II. Generic Equivalent to What Brand?:		<span style="border: 1px solid black; padding: 2px;">Paxil® CR</span>					
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer?		<span style="border: 1px solid black; padding: 2px;">Yes</span>		GLN:		<span style="border: 1px solid black; padding: 2px;">372241000003</span>	
Is product exempt from DSCSA?		<span style="border: 1px solid black; padding: 2px;">No</span>					
If yes, select exemption:		<span style="border: 1px solid black; padding: 2px;"></span>					
Other exemption - Write in:		<span style="border: 1px solid black; padding: 2px;"></span>					
Is product repackaged?		<span style="border: 1px solid black; padding: 2px;">No</span>		If Yes, was original product purchased direct from mfr?		<span style="border: 1px solid black; padding: 2px;"></span>	
Is product sold by manufacturer's exclusive distributor?		<span style="border: 1px solid black; padding: 2px;">No</span>		If yes, attach documentation from FDA.		<span style="border: 1px solid black; padding: 2px;"></span>	
Has FDA granted waiver/exception/exemption for product?		<span style="border: 1px solid black; padding: 2px;">No</span>					
GTIN AND HIBCC PRODUCT INFORMATION							
Saleable Unit of Measure		Quantity		HIBCC		GTIN-14	
<input checked="" type="checkbox"/> Item/Each		<span style="border: 1px solid black; padding: 2px;">1</span>		<span style="border: 1px solid black; padding: 2px;"></span>		<span style="border: 1px solid black; padding: 2px;">00372241029226</span>	
<input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack		<span style="border: 1px solid black; padding: 2px;">24</span>		<span style="border: 1px solid black; padding: 2px;"></span>		<span style="border: 1px solid black; padding: 2px;">20372241029220</span>	
<input checked="" type="checkbox"/> Case		<span style="border: 1px solid black; padding: 2px;">96</span>		<span style="border: 1px solid black; padding: 2px;"></span>		<span style="border: 1px solid black; padding: 2px;">40372241029224</span>	
<input checked="" type="checkbox"/> Pallet		<span style="border: 1px solid black; padding: 2px;">3456</span>		<span style="border: 1px solid black; padding: 2px;"></span>		<span style="border: 1px solid black; padding: 2px;">50372241029221</span>	
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