



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

Version 2021 Introduction Type: New Item Final Version Date: 10/20/2023

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*									
Company Name: Modavar Pharmaceuticals LLC (U.S. Agent for Cadila Pharmaceuticals Limited) Application: ANDA Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 206993 Medical Device Class, if applicable: _____ DUNS: 858949204 Proprietary Name (If Applicable) and Established Name: Fluoxetine Capsules 20 mg 1000 Selling Unit NDC: 72241-0008-11 Unit of Use NDC: _____ UPC: 372241008115 UDI _____ CVX Code: _____ MX Code: _____ Description: Fluoxetine Capsules 20 mg 1000 Active Ingredient(s): Fluoxetine URL for Additional Product Information: www.modavar.com Address: 1016 16th Street, NW, Ste. 602 Address 2: _____ City: Washington State: DC Zip: 20036 Key Contact: Lewis "Lew" Soars Email: Lewis@Modavar.com Phone Number: 202-355-9785 Fax: (202)355-9784 Product Therapeutic Classification: ANTIDEPRESSANT				a. Temperature – Indicate the USP temperature range for this product. Temperature Range: <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/> Other Temperature Range Requirement (write in): _____ Notes: _____ Is this product to be shipped to customers on ice? <input type="checkbox"/> No Is this product to be shipped to customers on dry ice? <input type="checkbox"/> No b. Contact for temperature excursion questions: Name: ModavarCS@eversana.com Number: 800-688-4697 Group E-mail: ModavarCS@eversana.com c. Special regulations for product in any states? <input type="checkbox"/> No Special returns requirements for this product? <input type="checkbox"/> No d. Store product (unit of sale) upright? <input type="checkbox"/> Yes Protect product (unit of sale) from light? <input type="checkbox"/> Yes e. Shelf life: <input type="text" value="24"/> Months Initial shelf life at launch (if different): <input type="text"/> Months									
ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION		ORDER INFORMATION									
The product is? a legend device? <input type="checkbox"/> No if yes, enter class # _____ a product kit? <input type="checkbox"/> No if yes, list NDCs of component parts reverse numbered? _____ co-licensed? <input type="checkbox"/> No latex-free? <input type="checkbox"/> Yes preservative-free? <input type="checkbox"/> Yes correctional institution block? <input type="checkbox"/> No opioid? <input type="checkbox"/> No Cannabinoid? <input type="checkbox"/> No If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/> _____ If Unit Dose, indicate NDC here: _____		Is the Product... Is the Product... Direct And Drop-Ship: <input type="checkbox"/> Neither Orphan Drug Status: _____ FDA Approval Status: _____ Allergens Present: See Package Insert - Country of Origin: India Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> No		Size: 1000 Strength: 20MG Dosage Form: Capsules Product Shape: capsules Product Color: green opaque cap and yellow opaque body Product Imprint: C29		Unit of Sale <input checked="" type="checkbox"/> Bottle <input type="checkbox"/> Box/Carton <input type="checkbox"/> Ampule <input type="checkbox"/> Glass <input type="checkbox"/> Tube <input type="checkbox"/> Vial Liquid Sgl <input type="checkbox"/> Vial Liquid Multi <input type="checkbox"/> Vial Powder Sgl <input type="checkbox"/> Vial Power Multi <input type="checkbox"/> Other: Write In _____				What is the NDC selling unit? <input type="text" value="1 bottle of 1000"/> (Write-in, e.g. 1 Box of 10 Vials) Minimum order quantity? <input type="checkbox"/> Yes If Yes, how many of which package type? <input type="text" value="6"/> Each <input type="text"/> Inner/ Carton/Pack <input type="text"/> Case			
FOR GENERIC DRUG PRODUCTS													
I. Orange Book Rating: <input type="text" value="AB"/> <input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable II. Generic Equivalent to What Brand?: <input type="text" value="Prozac®"/>													
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION													
Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Is product exempt from DSCSA? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, select exemption: _____ Other exemption - Write in: _____ Is product repackaged? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Is product sold by manufacturer's exclusive distributor? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Has FDA granted waiver/exception/exemption for product? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, attach documentation from FDA. _____								GLN: 0372241000003 GCP: _____ If yes, was original product purchased direct from mfr? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Provide source manufacturer for repackaged product _____					
GTIN AND HIBCC PRODUCT INFORMATION													
Saleable Unit of Measure <input checked="" type="checkbox"/> Item/Each <input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack <input checked="" type="checkbox"/> Case <input checked="" type="checkbox"/> Pallet		Saleable Quantity <input type="text" value="1"/> <input type="text" value="6"/> <input type="text" value="12"/> <input type="text" value="336"/>		HIBCC <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		GTIN-14 <input type="text" value="00372241008115"/> <input type="text" value="20372241008119"/> <input type="text" value="40372241008113"/> <input type="text" value="50372241008110"/>		Unit of Use GTIN-14 <input type="text"/>					
COST INFORMATION				WHOLESALE USE ONLY:									
Regular Cost _____ Invoice Cost (WAC) (\$) <input type="text" value="\$37.50"/> As of date: 10/20/2023				Vendor #: _____ Whsl. Code #: _____ Fineline Code: _____									

*Please provide any additional information on page 2.

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

See new p. 3 for Designated Drop Ship Only.

Signature:

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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION							
<p>Is this product (check all that apply):</p> <p>a. Cytotoxic? <input type="checkbox"/> No</p> <p>b. CA Prop. 65 Carcinogen or Reproductive Toxicant?</p> <p style="margin-left: 20px;">Is the product a CA Prop 65 carcinogen? <input type="checkbox"/> No</p> <p style="margin-left: 20px;">Is the product a CA Prop 65 reproductive toxicant? <input type="checkbox"/> No</p> <p style="margin-left: 20px;">Does the product label bear a CA Prop 65 warning? <input type="checkbox"/> No</p> <p>c. Contact Hazard? <input type="checkbox"/> No</p> <p>d. Does this product require special clean-up instructions? <input type="checkbox"/> No (If yes, attach SDS with special instructions.)</p> <p>e. Does the product contain DEHP? <input type="checkbox"/> No</p> <p>Is this product regulated for shipment by DOT? <input type="checkbox"/> No (if yes, answer a-e below and provide SDS)</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/> No</p> <p>Is this product regulated for shipment by IATA? <input type="checkbox"/> No (if yes, answer a-e below and provide SDS)</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/> No</p> <p>Is the product restricted for air shipment? If so, indicate restriction: <input type="checkbox"/> No</p> <p><input type="checkbox"/> Passenger</p> <p><input type="checkbox"/> Cargo</p> <p><input type="checkbox"/> Passenger & Cargo</p> <p>Is this a reportable quantity? <input type="checkbox"/></p> <p>RQ Threshold: <input type="text"/></p> <p>Is this a marine pollutant? <input type="checkbox"/></p> <p>Is this product shipped utilizing an authorized DOT exception or Special Permit? <input type="checkbox"/> No (if yes, identify method below)</p> <p><input type="checkbox"/> Limited Quantity</p> <p><input type="checkbox"/> Consumer Commodity, ORM-D</p> <p><input type="checkbox"/> Small Quantity (49 CFR 173.4)</p> <p><input type="checkbox"/> Special Permit; DOT-SP</p> <p><input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101);</p> <p>SP# <input type="text"/></p>	<div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p style="text-align: center; background-color: #002060; color: white; margin: 0;">SDS Hazard Classification</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;"><input type="checkbox"/> Organic</td> <td style="width: 50%; border: none;"><input type="checkbox"/> Corrosive</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Inorganic</td> <td style="border: none;"><input type="checkbox"/> Oxidizer</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Steroid/Androgen</td> <td style="border: none;"><input type="checkbox"/> Contact Hazard</td> </tr> </table> <p>Does the product have an Aerosol class? If yes, identify NFPA Storage Level: <input type="text"/></p> <p>NFPA Storage Level: <input type="text"/></p> <p>Is the product a NIOSH hazardous drug? <input type="checkbox"/></p> <p>If yes, indicate which: <input type="text"/></p> </div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 5px;"> <p style="text-align: center; background-color: #002060; color: white; margin: 0;">Hazardous Waste Identification</p> <p>EPA Hazardous Waste Code: <input type="text"/> Waste Characteristics: <input type="text"/></p> </div> <div style="border: 1px solid black; padding: 5px;"> <p style="text-align: center; background-color: #002060; color: white; margin: 0;">REMS or REGISTRY RESTRICTIONS</p> <p>Is there a REMS on this product? <input type="checkbox"/></p> <p>If Yes, is it managed with a pharmacy registry? <input type="checkbox"/></p> <p style="margin-left: 20px;">Website URL: <input type="text"/></p> <p>Med Guide Required <input type="checkbox"/></p> <p>Limited Distribution Requirement <input type="checkbox"/></p> <p>Comments / Details: (For example, iPledge program?) <input type="text"/></p> <p>REMS:</p> <p>REMS Program Manager Name: <input type="text"/> Phone: <input type="text"/></p> <p>Supplier Manages REMS registry exclusively: <input type="checkbox"/></p> <p style="margin-left: 20px;">Wholesale distributor support: <input type="checkbox"/></p> <p style="margin-left: 20px;">Provider Name: <input type="text"/> DEA #: <input type="text"/></p> <p style="margin-left: 20px;">Site Enrollment Number assigned by Supplier: <input type="text"/> NCPDP#: <input type="text"/></p> <p style="margin-left: 20px;">NPI #: <input type="text"/></p> <p>Comments <input type="text"/></p> <p>Registry:</p> <p>Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/></p> <p>Comments <input type="text"/></p> </div>	<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive	<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer	<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard
<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive						
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer						
<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard						
ADD'L STORAGE INFORMATION							
<p>Is the Product...</p> <p>Controlled Substance? <input type="checkbox"/> No <input type="checkbox"/> Yes Controlled Substance Code <input type="text"/></p> <p>Controlled by State(s)? <input type="checkbox"/> No <input type="checkbox"/> Yes Listed Chemical (List I or II) <input type="text"/></p> <p>ARCOS Reportable? <input type="checkbox"/> No <input type="checkbox"/> Yes If yes, indicate which: <input type="text"/></p> <p>Schedule No. <input type="text"/> Is it a scheduled listed chemical product?: <input type="checkbox"/></p>							
CLASS OF TRADE RESTRICTION:							
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input type="text"/></p>							
MISCELLANEOUS NOTES and/or Image of Product Barcode:							
<input style="width: 100%; height: 100%;" type="text"/>							



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

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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 <input type="checkbox"/> b. Autofax <input type="checkbox"/> c. Fax <input type="checkbox"/> d. Phone only <input type="checkbox"/> e. Supplier Web Site only <input type="checkbox"/> Minimum Order Quantity: <input type="text"/> Supplier's Customer Service Number: <input type="text"/> Contracted 3PL company / contact #: <input type="text"/> Name: <input type="text"/> Phone: <input type="text"/> Fax Number: <input type="text"/> Fax Number: <input type="text"/> Phone No.: <input type="text"/> Site Address: <input type="text"/>	Purchase order daily receipt cut off time by supplier Cut off time: <input type="text"/> Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days Ships same day for next day receipt: <input type="checkbox"/> Ships for second day receipt: <input type="checkbox"/> Ships regular ground for 3-10 days receipt: <input type="checkbox"/>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: <input type="text"/> Drop Ship service fee billed with each order: <input type="text"/> Drop Ship miscellaneous fees billed: <input type="text"/> Comments: <input type="text"/>	Overnight receipt available: <input type="checkbox"/> PO Receipt cut off time: <input type="text"/> Days of week overnight is available: <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday Priority Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/>
Class of Trade Restriction:	Saturday Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Order receipt method: <input type="text"/> Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="text"/> Overnight Fees apply: <input type="checkbox"/> Other fees apply: <input type="checkbox"/>
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Restricted to retail pharmacy only: <input type="checkbox"/> Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> Restricted from US territories? (explain in comments) <input type="checkbox"/> Comments: <input type="text"/>	
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: <input type="text"/> Physician Name: <input type="text"/> Physician/Clinic Phone #: <input type="text"/> Physician State License #: <input type="text"/> Physician/Clinic DEA #: <input type="text"/> Physician/Clinic Specialty: <input type="text"/>	Contact # if product is received damaged: <input type="text"/> Is product returnable for credit: <input type="checkbox"/> URL/Link to returns policy: <input type="text"/> Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> If so, which states? Other requirements? Comments? <input type="text"/>
Miscellaneous Notes:	ADDITIONAL INFORMATION
<input type="text"/>	Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>