



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

Version 2020 Introduction Type: New Item Final Version Date:

PRODUCT INFORMATION	
Company Name:	Auromedics Pharma LLC
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	210968
DUNS:	968961354
Proprietary Name (If Applicable) and Established Name:	Olanzapine for Injection
Selling Unit NDC:	55150-308-01
Unit of Use NDC:	55150-308-01
UPC:	355150308019
CVX Code:	
MXV Code:	
Description:	Olanzapine for Injection 10mg / Vial (Single Dose Vial) Mono Pack
Active Ingredient(s):	Olanzapine
URL for Additional Product Information:	
Address:	279 Princeton-Hightstown Road
City:	East Windsor
Key Contact:	
Phone Number:	888-238-7880
Product Therapeutic Classification:	2nd generation atypical antipsychotic
Application:	ANDA

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
Temperature Range	Controlled Room – between 20 and 25 C (68° – 77° F)
Other Temperature Range Requirement (write in)	After Reconstitution: use immediately (within 1 hour). May store at 20° to 25° C (68° to 77° F)
Notes	Discard any unused portion.
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	No
b. Contact for temperature excursion questions:	
Name:	Steve Lucas
Number:	732-823-4122
Group E-mail:	slucas@aurobindousa.com
c. Special regulations for product in any states?	
Special returns requirements for this product?	No
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	No
e. Shelf life:	
Initial shelf life at launch (if different):	24 Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device? if yes, enter class #	No	Is the Product... Direct-Ship Only	1 x 5 mL single dose vial
if yes, list NDCs of component parts	No	Is the Product... Orphan Drug Status	10 mg per vial
reverse numbered?	No	FDA Approval Status	Lyo (Powder)
co-licensed?	No	Allergens Present	Vial Pack
latex-free?	Yes	Country of Origin	India
preservative-free?	Yes	Is this product covered under the Trade Agreements Act (TAA)?	No
correctional institution block?	No		
opioid?	No		
Cannabinoid?	No		
If Unit Dose, is item bar coded to unit dose for hospital scanning?			
If Unit Dose, indicate NDC here:			

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 Carton of 1 Vial
<input checked="" type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	Minimum order quantity? Yes
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	If Yes, how many of which package type?
<input type="checkbox"/> Vial Powder Sgl	<input type="checkbox"/> Each
<input type="checkbox"/> Vial Power Multi	<input type="checkbox"/> Inner/Carton/Pack
<input type="checkbox"/> Other: Write In	<input type="text" value="1"/> Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AP
II. Generic Equivalent to What Brand?:	Zyprexa
<input type="checkbox"/> Authorized Generic	*If Authorized Generic, other section fields are not applicable

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
<input type="text" value="1"/> vial	<input checked="" type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input checked="" type="checkbox"/> Gram
	<input type="checkbox"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	Yes
Is product exempt from DSCSA?	No
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	No
Is product sold by manufacturer's exclusive distributor?	No
Has FDA granted waiver/exception/exemption for product?	No
GLN:	
If Yes, was original product purchased direct from mfr?	
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Width	Height		
Box/Carton/Bundle/Inner Pack:						
Case:	9.737	18.504	9.055	7.48	1253.3018	100 packs
Pallet:	714.61	48	40	57.36	110131.2	70 cases

GTIN AND HIBCC PRODUCT INFORMATION				
Saleable Unit of Measure	Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1		00355150308019	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input type="checkbox"/> Case	100		50355150308014	
<input type="checkbox"/> Pallet	70		70355150308018	

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$35.44	Whsl. Code #:	
As of date:		Fineline Code:	

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION							
<p>Is this product (check all that apply):</p> <p>a. Cytotoxic? No</p> <p>b. CA Prop. 65 Carcinogen or Reproductive Toxicant? No</p> <p style="padding-left: 20px;">Is the product a CA Prop 65 carcinogen? No</p> <p style="padding-left: 20px;">Is the product a CA Prop 65 reproductive toxicant? No</p> <p style="padding-left: 20px;">Does the product label bear a CA Prop 65 warning? No</p> <p>c. Contact Hazard? No</p> <p>d. Does this product require special clean-up instructions? No (if yes, attach SDS with special instructions.)</p> <p>e. Does the product contain DEHP? No</p> <p>Is this product regulated for shipment by DOT? No (if yes, answer a-e below and provide SDS)</p> <p>a. UN/Identification Number <input style="width: 100%;" type="text"/></p> <p>b. Proper Shipping Name <input style="width: 100%;" type="text"/></p> <p>c. DOT Hazard Class <input style="width: 100%;" type="text"/></p> <p>d. Packing Group <input style="width: 100%;" type="text"/></p> <p>e. Inhalation Hazard? No</p> <p>Is this product regulated for shipment by IATA? No (if yes, answer a-e below and provide SDS)</p> <p>a. UN/Identification Number <input style="width: 100%;" type="text"/></p> <p>b. Proper Shipping Name <input style="width: 100%;" type="text"/></p> <p>c. DOT Hazard Class <input style="width: 100%;" type="text"/></p> <p>d. Packing Group <input style="width: 100%;" type="text"/></p> <p>e. Inhalation Hazard? No</p> <p>Is the product restricted for air shipment? If so, indicate restriction:</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 style="width: 50px;" type="text"/></p> <p>Is this a marine pollutant? No</p> <p>Is this product shipped utilizing an authorized DOT exception or Special Permit? 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 style="width: 50px;" type="text"/></p>	<div style="border: 1px solid black; background-color: #003366; color: white; padding: 2px; text-align: center;">SDS Hazard Classification</div> <table style="width: 100%; border: none;"> <tr> <td style="border: none;"><input type="checkbox"/> Organic</td> <td style="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><input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input style="width: 50px;" type="text"/></p> <p>Is the product a NIOSH hazardous drug? No</p> <p>If yes, indicate which: <input style="width: 100%;" type="text"/></p>	<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						
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<p>a. UN/Identification Number <input style="width: 100%;" type="text"/></p> <p>b. Proper Shipping Name <input style="width: 100%;" type="text"/></p> <p>c. DOT Hazard Class <input style="width: 100%;" type="text"/></p> <p>d. Packing Group <input style="width: 100%;" type="text"/></p> <p>e. Inhalation Hazard? No</p>	<div style="border: 1px solid black; background-color: #003366; color: white; padding: 2px; text-align: center;">Hazardous Waste Identification</div> <p>EPA Hazardous Waste Code: <input style="width: 150px;" type="text"/></p> <p>Waste Characteristics: <input style="width: 100%;" type="text"/></p>						
<p>a. UN/Identification Number <input style="width: 100%;" type="text"/></p> <p>b. Proper Shipping Name <input style="width: 100%;" type="text"/></p> <p>c. DOT Hazard Class <input style="width: 100%;" type="text"/></p> <p>d. Packing Group <input style="width: 100%;" type="text"/></p> <p>e. Inhalation Hazard? No</p>	<div style="border: 1px solid black; background-color: #003366; color: white; padding: 2px; text-align: center;">REMS or REGISTRY RESTRICTIONS</div> <p>Is there a REMS on this product? No</p> <p>If Yes, is it managed with a pharmacy registry? <input style="width: 50px;" type="text"/></p> <p>Website URL: <input style="width: 100%;" type="text"/></p> <p>Med Guide Required <input style="width: 50px;" type="text"/></p> <p>Limited Distribution Requirement <input style="width: 50px;" type="text"/></p> <p>Comments / Details: (For example, iPledge program?) <input style="width: 100%;" type="text"/></p> <p>REMS:</p> <p>REMS Program Manager Name: <input style="width: 100%;" type="text"/> Phone: <input style="width: 50px;" type="text"/></p> <p>Supplier Manages REMS registry exclusively: <input style="width: 50px;" type="text"/></p> <p>Wholesale distributor support: <input style="width: 50px;" type="text"/></p> <p>Provider Name: <input style="width: 100%;" type="text"/> DEA #: <input style="width: 50px;" type="text"/></p> <p>Site Enrollment Number assigned by Supplier: <input style="width: 100%;" type="text"/> PCPDP#: <input style="width: 50px;" type="text"/></p> <p>NPI #: <input style="width: 50px;" type="text"/></p> <p>Comments <input style="width: 100%;" type="text"/></p> <p>Registry:</p> <p>Registry Program Contact Name: <input style="width: 100%;" type="text"/> Phone: <input style="width: 50px;" type="text"/></p> <p>Comments <input style="width: 100%;" type="text"/></p>						
<div style="border: 1px solid black; background-color: #003366; color: white; padding: 2px; text-align: center;">ADD'L STORAGE INFORMATION</div> <p>Is the Product...</p> <p>Controlled Substance? No Controlled Substance Code <input style="width: 50px;" type="text"/></p> <p>Controlled by State(s)? No Listed Chemical (List I or II) <input style="width: 50px;" type="text"/></p> <p>ARCOS Reportable? No If yes, indicate which: <input style="width: 50px;" type="text"/></p> <p>Schedule No. <input style="width: 50px;" type="text"/> Is it a scheduled listed chemical product?: No</p>	<div style="border: 1px solid black; background-color: #003366; color: white; padding: 2px; text-align: center;">RETURN INSTRUCTIONS</div> <p>Contact tel. # if product received damaged: <input style="width: 100%;" type="text" value="888-238-7880"/></p> <p>Is product returnable for credit: Yes</p> <p>URL/Link to returns policy: <input style="width: 100%;" type="text" value="http://auomedics.com/policies/return-policy/"/></p> <p>Special regulations or returns requirements for this product in certain states? <input style="width: 50px;" type="text"/></p> <p>If so, which states? Other requirements? Comments? <input style="width: 100%;" type="text"/></p>						
<div style="border: 1px solid black; background-color: #003366; color: white; padding: 2px; text-align: center;">CLASS OF TRADE RESTRICTION:</div> <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes</p> <p>Restricted to retail pharmacy only: No</p> <p>Restricted to hospital, clinics, and physician offices only: No</p> <p>Restricted from US territories? (explain in comments) No</p> <p>Comments: <input style="width: 100%;" type="text"/></p>	<div style="border: 1px solid black; background-color: #003366; color: white; padding: 2px; text-align: center;">MISCELLANEOUS NOTES and/or Image of Product Barcode:</div> <p><input style="width: 100%; height: 20px;" type="text"/></p>						



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Version 2020

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: <ul style="list-style-type: none"> a. EDI <input type="checkbox"/> b. Autofax <input type="checkbox"/> Fax Number: <input type="text"/> c. Fax <input type="checkbox"/> Fax Number: <input type="text"/> d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/> e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/> Minimum Order Quantity: <input type="text"/> Supplier's Customer Service Number: <input type="text"/> Contracted 3PL company / contact #: Name: <input type="text"/> Phone: <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: <table border="1" style="margin-left: 20px;"> <tr><td><input type="checkbox"/></td><td>Monday</td></tr> <tr><td><input type="checkbox"/></td><td>Tuesday</td></tr> <tr><td><input type="checkbox"/></td><td>Wednesday</td></tr> <tr><td><input type="checkbox"/></td><td>Thursday</td></tr> <tr><td><input type="checkbox"/></td><td>Friday</td></tr> </table> Priority Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Saturday Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="checkbox"/> Overnight Fees apply: <input type="checkbox"/> Other fees apply: <input type="checkbox"/>	<input type="checkbox"/>	Monday	<input type="checkbox"/>	Tuesday	<input type="checkbox"/>	Wednesday	<input type="checkbox"/>	Thursday	<input type="checkbox"/>	Friday
<input type="checkbox"/>	Monday										
<input type="checkbox"/>	Tuesday										
<input type="checkbox"/>	Wednesday										
<input type="checkbox"/>	Thursday										
<input type="checkbox"/>	Friday										
Class of Trade Restriction:											
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:											
<input type="text"/>											
	ADDITIONAL INFORMATION										
	Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>										