



<input type="checkbox"/> Final Version	Date:	3/30/2015
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PRODUCT INFORMATION																																																																											
Company Name:		Amneal Pharmaceuticals		Application: ANDA																																																																							
Application Number for NDA/ANDA/BLA, Med Device:		202960																																																																									
Rx Product/Proprietary Name:		Atovaquone Oral Suspension, USP 750mg/5mL																																																																									
NDC:	65162-693-88	UPC:	3-6516269388-1																																																																								
CVX Code:		MVX Code:																																																																									
Description:	Atovaquone Suspension (bright yellow, citrus flavored) containing 750mg atovaquone in each teaspoonful (5mL).																																																																										
Active ingredients:	Atovaquone																																																																										
URL for Additional Product Information:																																																																											
Address:	118 Beaver Trail		Address 2:																																																																								
City:	Glasgow	State:	KY	Zip:	42141																																																																						
Key Contact:		Email:																																																																									
Phone Number:		Fax:	866-525-7271																																																																								
FOR GENERIC DRUG PRODUCTS																																																																											
I. Orange Book Rating:	AB	II. Brand Name:	Mepron																																																																								
III. Generic Equivalent for Brand:	Atovaquone Oral Suspension, USP 750mg/5mL																																																																										
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION																																																																											
Does supplier meet DSCSA definition of manufacturer?	Yes		DUNS:	82-774-8190																																																																							
Is product exempt from DSCSA?	No																																																																										
If yes, select exemption: Other exemption - Write in:																																																																											
Is product repackaged?	No	If Yes, was original product purchased direct from mfr?																																																																									
Is product sold by manufacturer's exclusive distributor?	No																																																																										
Are any waivers granted for product ID/barcode?	No	If yes, attach documentation from FDA																																																																									
ADDITIONAL PRODUCT INFORMATION			ITEM AND PACKING INFORMATION																																																																								
Is the Product... Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Code: Hazardous Material/Cytotoxic Agent?	Direct Ship Item 	<table><tr><th colspan="2">ORDER INFORMATION</th></tr><tr><td>Unit of Sale</td><td>What is the NDC selling unit?</td></tr><tr><td>x Bottle</td><td>1 Bottle of 210mL</td></tr><tr><td>Box/ Carton</td><td>(Write-in, e.g. 1 Box of 10 Vials)</td></tr><tr><td>Ampule</td><td>Minimum order quantity? Yes</td></tr><tr><td>Glass</td><td>If Yes, how many of which package type?</td></tr><tr><td>Tube</td><td>12 Each</td></tr><tr><td>Vial Liquid Sgl</td><td>Inner/ Carton/Pack</td></tr><tr><td>Vial Liquid Multi</td><td>Case</td></tr><tr><td>Vial Powder Sgl</td><td></td></tr><tr><td>Vial Power Multi</td><td></td></tr><tr><td>Other: Write In</td><td></td></tr></table>	ORDER INFORMATION		Unit of Sale	What is the NDC selling unit?	x Bottle	1 Bottle of 210mL	Box/ Carton	(Write-in, e.g. 1 Box of 10 Vials)	Ampule	Minimum order quantity? Yes	Glass	If Yes, how many of which package type?	Tube	12 Each	Vial Liquid Sgl	Inner/ Carton/Pack	Vial Liquid Multi	Case	Vial Powder Sgl		Vial Power Multi		Other: Write In		<table><tr><th>Weight Lbs.</th><th colspan="3">Dimensions (US msmts.)</th><th>Volume (Cube)</th><th># Pieces:</th></tr><tr><th></th><th>Depth</th><th>Height</th><th>Width:</th><th></th><th></th></tr><tr><td>Item:</td><td>243.8gm</td><td></td><td>5.18"</td><td>2.32"</td><td></td></tr><tr><td>Box/ Carton:</td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>Case:</td><td>5.95 lbs</td><td>10.75"</td><td>5.625"</td><td>8"</td><td></td></tr><tr><td>Pallet:</td><td></td><td>40"</td><td>48"</td><td>40"</td><td>96</td></tr><tr><td>UPC:</td><td>Case:</td><td colspan="4"></td></tr><tr><td></td><td>Carton:</td><td colspan="4"></td></tr></table>	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:		Depth	Height	Width:			Item:	243.8gm		5.18"	2.32"		Box/ Carton:						Case:	5.95 lbs	10.75"	5.625"	8"		Pallet:		40"	48"	40"	96	UPC:	Case:						Carton:				
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Is Item... If Unit Dose, is item bar coded to unit dose for hospital scanning? Is it reverse numbered?	 	<table><tr><th>PHARMACY ORDER / BILL UNIT</th><th>Other Product Information</th></tr><tr><td>Rec. sell unit to customer?</td><td>Size/Strength/Form:</td></tr><tr><td></td><td>210mL; 750mg/5mL; Oral Suspension</td></tr><tr><td>(Write-in, e.g. 1 Vial)</td><td></td></tr><tr><td>Rx billing unit to pharmacy:</td><td>Product Shape:</td></tr><tr><td>Each</td><td>Product Color:</td></tr><tr><td>Gram</td><td>Bright Yellow</td></tr><tr><td>Milliliter</td><td>Product Imprint:</td></tr></table>	PHARMACY ORDER / BILL UNIT	Other Product Information	Rec. sell unit to customer?	Size/Strength/Form:		210mL; 750mg/5mL; Oral Suspension	(Write-in, e.g. 1 Vial)		Rx billing unit to pharmacy:	Product Shape:	Each	Product Color:	Gram	Bright Yellow	Milliliter	Product Imprint:	<table><tr><th colspan="3">COST INFORMATION</th></tr><tr><th>Regular Cost Per Unit of Sale (\$)</th><th>Invoice Cost (WAC) (\$)</th><th>Federal Excise Tax Per Unit of Sale</th></tr><tr><td></td><td>\$1,102.56</td><td></td></tr><tr><td colspan="3">As of date:</td></tr></table>	COST INFORMATION			Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale		\$1,102.56		As of date:																																														
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Whsl. Code #:																																																																											
Fineline Code:																																																																											

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

***Please provide any additional information on page 2.**

See new p. 3 for Designated Drop Ship Only.

Signature: _____



Standard Pharmaceutical Product Information (Page 2)

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
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant? ☐ No
- ☐ Carcinogen
- ☐ Reproductive Toxicant
- ☐ Both
- ☐ Warning appears on label
- c. Contact Hazard? ☐ Yes
- d. Does this product require special clean-up instructions?
(If yes, attach SDS with special instructions.) ☐ Yes
- e. Does the product contain DEHP? ☐

Hazardous Waste Identification

EPA Hazardous Waste Code:

Is this product regulated for shipment by the DOT? ☐

Is this a reportable quantity?

RQ Threshold:

Is this a marine pollutant? ☐

Is this product shipped utilizing an authorized DOT exception or Special Permit?

☐ (if yes, identify method below)

- ☐ Limited Quantity
- ☐ Consumer Commodity, ORM-D
- ☐ Small Quantity (49 CFR 173.4)
- ☐ Special Permit; DOT-SP
- ☐ Special Provision (listed in Column 7 of 49 CFR 172.101);
- SP#

Is the product restricted for air shipment? If so, indicate restriction:

- ☐ Passenger
- ☐ Cargo
- ☐ Passenger & Cargo

(if yes, answer a-d below and provide SDS)

- a. DOT Hazard Class
- b. UN/ID Number
- c. Packing Group
- d. Inhalation Hazard?

ADDITIONAL PRODUCT INFORMATION - Serialization

Serialized?	Yes	Level	How?	GTIN-14
Serialized?	<input type="checkbox"/>	Item	<input type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/> RFID
If not, when?	<input type="text"/>	Box/Cartron	<input type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/> RFID
Items aggregated to case?	<input type="checkbox"/>	Case	<input checked="" type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/> RFID
		Pallet	<input type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/> RFID

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?

☐ No

If Yes, is it managed with a pharmacy registry?

Website URL:

Comments / Details: (For example, iPledge program?)

ADD'L STORAGE INFORMATION

Please check as appropriate for this product.

- ☒ Organic ☐ Inorganic
- ☐ Antineoplastic ☐ Steroid/Androgen
- ☐ Corrosive ☐ Oxidizer

☐ Aerosol Class; Identify NFPA Storage Level:

RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

866-525-7270

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?

☐ Listed Chemical (List I or II) (Indicate or Write-in below):

- ☐ Ephedrine
- ☐ Pseudoephedrine
- ☐ Phenylpropanolamine
- ☐ Iodine ($\geq 2.2\%$)
- ☐ Other:

CLASS OF TRADE RESTRICTION:

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:

ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here:

MISCELLANEOUS NOTES and/or Image of Product Barcode:



Standard Pharmaceutical Product Information (Page 3)

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