



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:

Final Version Date:

PRODUCT INFORMATION		SPECIAL HANDLING AND STORAGE REQUIREMENTS*																																										
Company Name: <input type="text" value="AuroMedics Pharma LLC"/> Application: <input type="text" value="ANDA"/> Application Number for NDA/ANDA/BLA, Med Device: <input type="text" value="205612"/> DUNS: <input type="text"/> Rx Product/Proprietary Name: <input type="text" value="Ropivacaine Hydrochloride Injection, USP 0.2% 40 mg/20 mL (2 mg/mL)"/> NDC: <input type="text" value="55150-195-20"/> UPC: <input type="text" value="355150195206"/> CVX Code: <input type="text"/> MVX Code: <input type="text"/> Description: <input type="text" value="Ropivacaine Hydrochloride Injection, USP 0.2% 40 mg/20 mL (2 mg/mL)"/> Active ingredients: <input type="text"/> URL for Additional Product Information: <input type="text" value="www.auromedics.com"/> Address: <input type="text" value="6 Wheeling Road"/> Address 2: <input type="text"/> City: <input type="text" value="Dayton"/> State: <input type="text" value="NJ"/> Zip: <input type="text" value="08810"/> Key Contact: <input type="text"/> Email: <input type="text"/> Phone Number: <input type="text" value="888-238-7880"/> Fax: <input type="text" value="732-355-9449"/>		a. Temperature – Indicate the USP temperature range for this product. <input type="checkbox"/> I. Freezer – between -25 and -10 C (-13° – 14° F) <input type="checkbox"/> II. Cold – between 2 and 8 C (36° – 46° F) <input type="checkbox"/> III. Cool – between 8 and 15 C (46° – 59° F) <input checked="" type="checkbox"/> IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F) <input type="checkbox"/> V. Avoid Excessive Heat – above 40 C (>104° F) <input type="checkbox"/> VI. Other Temperature Range Requirement (write in) <input type="text"/> <input type="checkbox"/> VII. No Requirement b. Contact for temperature excursion questions: Name: <input type="text" value="Steve Lucas"/> Number: <input type="text" value="732-823-4122"/> Is this product to be shipped to customers on ice? <input type="text" value="No"/> Is this product to be shipped to customers on dry ice? <input type="text" value="No"/> c. Special regulations for product in certain states? <input type="text" value="No"/> Special returns requirements for this product? <input type="text" value="No"/> d. Store product (unit of sale) upright? <input type="text" value="No"/> Protect product (unit of sale) from light? <input type="text" value="No"/> e. Shelf life: <input type="text" value="24"/> Months Initial shelf life at launch (if different): <input type="text"/> Months																																										
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Rx Product/Proprietary Name:	<input type="text" value="Ropivacaine Hydrochloride Injection, USP 0.5% 100 mg/20 mL (5 mg/mL)"/>		
NDC:	<input type="text" value="55150-197-20"/>	UPC:	<input type="text" value="355150197200"/>
CVX Code:	<input type="text"/>	MVX Code:	<input type="text"/>
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Address:	<input type="text" value="6 Wheeling Road"/>	Address 2:	<input type="text"/>
City:	<input type="text" value="Dayton"/>	State:	<input type="text" value="NJ"/>
Key Contact:	<input type="text"/>	Email:	<input type="text" value="08810"/>
Phone Number:	<input type="text" value="888-238-7880"/>	Fax:	<input type="text" value="732-355-9449"/>

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
<input type="checkbox"/>	I. Freezer – between -25 and -10 C (-13° – 14° F)
<input type="checkbox"/>	II. Cold – between 2 and 8 C (36° – 46° F)
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<input type="checkbox"/>	V. Avoid Excessive Heat – above 40 C (>104° F)
<input type="checkbox"/>	VI. Other Temperature Range Requirement (write in) <input type="text"/>
<input type="checkbox"/>	VII. No Requirement
b. Contact for temperature excursion questions:	
Name:	<input type="text" value="Steve Lucas"/>
Number:	<input type="text" value="732-823-4122"/>
Is this product to be shipped to customers on ice?	<input type="text" value="No"/>
Is this product to be shipped to customers on dry ice?	<input type="text" value="No"/>
c. Special regulations for product in certain states?	
Special returns requirements for this product?	<input type="text" value="No"/>
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	<input type="text" value="No"/>
e. Shelf life:	
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I. Orange Book Rating:	<input type="text" value="AP"/>
II. Brand Name:	<input type="text" value="Naropin"/>
III. Generic Equivalent for Brand:	<input type="text" value="ropivacaine"/>

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input checked="" type="text" value="Yes"/>
Is product exempt from DSCSA?	<input type="text" value="No"/>
If yes, select exemption:	<input type="text"/>
Other exemption - Write in:	<input type="text"/>
Is product repackaged?	<input type="text" value="No"/>
If Yes, was original product purchased direct from mfr?	<input type="text"/>
Is product sold by manufacturer's exclusive distributor?	<input type="text" value="No"/>
Are any waivers granted for product ID/barcode?	<input type="text" value="No"/>
If yes, attach documentation from FDA	<input type="text"/>

ADDITIONAL PRODUCT INFORMATION		ORDER INFORMATION	
Is the Product... Direct Ship Item	<input type="text"/>	Unit of Sale	<input checked="" type="checkbox"/> Bottle
Legend Device?	<input type="text" value="No"/>	What is the NDC selling unit?	<input type="text" value="25 Vials in one Carton. The Carton NDC No. is 55150-197-20"/>
State Control?	<input type="text" value="No"/>	(Write-in, e.g. 1 Box of 10 Vials)	<input type="text"/>
ARCOS reportable?	<input type="text" value="No"/>	Minimum order quantity?	<input checked="" type="text" value="Yes"/>
Co-Licensed?	<input type="text" value="No"/>	If Yes, how many of which package type?	<input type="text"/>
Controlled Substance?	<input type="text" value="No"/>	<input type="text"/>	Each
Schedule No.?	<input type="text"/>	<input type="text" value="4"/>	Inner/ Carton/ Pack
(incl. N for non-narcotic)	<input type="text"/>	<input type="text"/>	Case
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Hazardous Material/Cytotoxic Agent?	<input type="text" value="No"/>		
Is Item...	<input type="text"/>		
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text"/>		
Is it reverse numbered?	<input type="text"/>		

ITEM AND PACKING INFORMATION						
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WHOLESALE USE ONLY:		PHARMACY ORDER / BILL UNIT		Other Product Information		COST INFORMATION		
Vendor #:	<input type="text"/>	Rec. sell unit to customer?	<input type="text"/>	Size/Strength/Form:	<input type="text"/>	Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
Whsl. Code #:	<input type="text"/>	(Write-in, e.g. 1 Vial)		Product Shape:	<input type="text"/>		\$350.00	
Fineline Code:	<input type="text"/>	Rx billing unit to pharmacy:	<input type="text"/>	Product Color:	<input type="text"/>			
		<input type="checkbox"/> Each		Product Imprint:	<input type="text"/>			
		<input type="checkbox"/> Gram						
		<input type="checkbox"/> Milliliter						

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Company Name: <input type="text" value="AuroMedics Pharma LLC"/> Application: <input type="text" value="ANDA"/> Application Number for NDA/ANDA/BLA, Med Device: <input type="text" value="205612"/> DUNS: <input type="text"/> Rx Product/Proprietary Name: <input type="text" value="Ropivacaine Hydrochloride Injection, USP 0.5% 150 mg/30 mL (5 mg/mL)"/> NDC: <input type="text" value="55150-198-30"/> UPC: <input type="text" value="355150198306"/> CVX Code: <input type="text"/> MVX Code: <input type="text"/> Description: <input type="text" value="Ropivacaine Hydrochloride Injection, USP 0.5% 150 mg/30 mL (5 mg/mL)"/> Active ingredients: <input type="text"/> URL for Additional Product Information: <input type="text" value="www.auromedics.com"/> Address: <input type="text" value="6 Wheeling Road"/> Address 2: <input type="text"/> City: <input type="text" value="Dayton"/> State: <input type="text" value="NJ"/> Zip: <input type="text" value="08810"/> Key Contact: <input type="text"/> Email: <input type="text"/> Phone Number: <input type="text" value="888-238-7880"/> Fax: <input type="text" value="732-355-9449"/>		a. Temperature – Indicate the USP temperature range for this product. <input type="checkbox"/> I. Freezer – between -25 and -10 C (-13° – 14° F) <input type="checkbox"/> II. Cold – between 2 and 8 C (36° – 46° F) <input type="checkbox"/> III. Cool – between 8 and 15 C (46° – 59° F) <input checked="" type="checkbox"/> IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F) <input type="checkbox"/> V. Avoid Excessive Heat – above 40 C (>104° F) <input type="checkbox"/> VI. Other Temperature Range Requirement (write in) <input type="text"/> <input type="checkbox"/> VII. No Requirement b. Contact for temperature excursion questions: Name: <input type="text" value="Steve Lucas"/> Number: <input type="text" value="732-823-4122"/> Is this product to be shipped to customers on ice? <input type="text" value="No"/> Is this product to be shipped to customers on dry ice? <input type="text" value="No"/> c. Special regulations for product in certain states? <input type="text" value="No"/> Special returns requirements for this product? <input type="text" value="No"/> d. Store product (unit of sale) upright? <input type="text" value="No"/> Protect product (unit of sale) from light? <input type="text" value="No"/> e. Shelf life: <input type="text" value="24"/> Months Initial shelf life at launch (if different): <input type="text"/> Months																																											
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Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.																																													
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Standard Pharmaceutical Product Information (Rx Product Only)

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Introduction Type:

Final Version Date:

PRODUCT INFORMATION		SPECIAL HANDLING AND STORAGE REQUIREMENTS*							
Company Name: <input type="text" value="AuroMedics Pharma LLC"/> Application: <input type="text" value="ANDA"/> Application Number for NDA/ANDA/BLA, Med Device: <input type="text" value="205612"/> DUNS: <input type="text"/> Rx Product/Proprietary Name: <input type="text" value="Ropivacaine Hydrochloride Injection, USP 0.75% 150 mg/20 mL (7.5 mg/mL)"/> NDC: <input type="text" value="55150-199-20"/> UPC: <input type="text" value="355150199204"/> CVX Code: <input type="text"/> MVX Code: <input type="text"/> Description: <input type="text" value="Ropivacaine Hydrochloride Injection, USP 0.75% 150 mg/20 mL (7.5 mg/mL)"/> Active ingredients: <input type="text"/> URL for Additional Product Information: <input type="text" value="www.auromedics.com"/> Address: <input type="text" value="6 Wheeling Road"/> Address 2: <input type="text"/> City: <input type="text" value="Dayton"/> State: <input type="text" value="NJ"/> Zip: <input type="text" value="08810"/> Key Contact: <input type="text"/> Email: <input type="text"/> Phone Number: <input type="text" value="888-238-7880"/> Fax: <input type="text" value="732-355-9449"/>		a. Temperature – Indicate the USP temperature range for this product. <input type="checkbox"/> I. Freezer – between -25 and -10 C (-13° – 14° F) <input type="checkbox"/> II. Cold – between 2 and 8 C (36° – 46° F) <input type="checkbox"/> III. Cool – between 8 and 15 C (46° – 59° F) <input checked="" type="checkbox"/> IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F) <input type="checkbox"/> V. Avoid Excessive Heat – above 40 C (>104° F) <input type="checkbox"/> VI. Other Temperature Range Requirement (write in) <input type="text"/> <input type="checkbox"/> VII. No Requirement b. Contact for temperature excursion questions: Name: <input type="text" value="Steve Lucas"/> Number: <input type="text" value="732-823-4122"/> Is this product to be shipped to customers on ice? <input type="text" value="No"/> Is this product to be shipped to customers on dry ice? <input type="text" value="No"/> c. Special regulations for product in certain states? <input type="text" value="No"/> Special returns requirements for this product? <input type="text" value="No"/> d. Store product (unit of sale) upright? <input type="text" value="No"/> Protect product (unit of sale) from light? <input type="text" value="No"/> e. Shelf life: <input type="text" value="24"/> Months Initial shelf life at launch (if different): <input type="text"/> Months							
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WHOLESALE USE ONLY:		PHARMACY ORDER / BILL UNIT Rec. sell unit to customer? <input type="text"/> (Write-in, e.g. 1 Vial) Rx billing unit to pharmacy: <input type="checkbox"/> Each <input type="checkbox"/> Gram <input type="checkbox"/> Milliliter							
		Other Product Information Size/Strength/Form: <input type="text"/> Product Shape: <input type="text"/> Product Color: <input type="text"/> Product Imprint: <input type="text"/>							
		COST INFORMATION <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 33%;">Regular Cost Per Unit of Sale (\$)</th> <th style="width: 33%;">Invoice Cost (WAC) (\$)</th> <th style="width: 33%;">Federal Excise Tax Per Unit of Sale</th> </tr> </thead> <tbody> <tr> <td style="height: 40px;"></td> <td style="text-align: center;">\$450.00</td> <td></td> </tr> </tbody> </table> <p style="text-align: right;">As of date: <input type="text" value="10/28/2016"/></p>		Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale		\$450.00	
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale							
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Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.									
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		Signature: <input type="text"/>							



Standard Pharmaceutical Product Information (Rx Product Only)

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Introduction Type:

Final Version Date:

PRODUCT INFORMATION	
Company Name:	AuroMedics Pharma LLC
Application Number for NDA/ANDA/BLA, Med Device:	205612
DUNS:	
Rx Product/Proprietary Name:	Ropivacaine Hydrochloride Injection, USP 1% 100 mg/10 mL (10 mg/mL)
NDC:	55150-200-10
CVX Code:	
UPC:	355150200108
MVX Code:	
Description:	Ropivacaine Hydrochloride Injection, USP 1% 100 mg/10 mL (10 mg/mL)
Active ingredients:	
URL for Additional Product Information:	www.auromedics.com
Address:	6 Wheeling Road
City:	Dayton
Key Contact:	
Phone Number:	888-238-7880
State:	NJ
Address 2:	
Email:	
Fax:	732-355-9449
Zip:	08810

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
<input type="checkbox"/>	I. Freezer – between -25 and -10 C (-13° – 14° F)
<input type="checkbox"/>	II. Cold – between 2 and 8 C (36° – 46° F)
<input type="checkbox"/>	III. Cool – between 8 and 15 C (46° – 59° F)
<input checked="" type="checkbox"/>	IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F)
<input type="checkbox"/>	V. Avoid Excessive Heat – above 40 C (>104° F)
<input type="checkbox"/>	VI. Other Temperature Range Requirement (write in) <input type="text"/>
<input type="checkbox"/>	VII. No Requirement
b. Contact for temperature excursion questions:	
Name:	Steve Lucas
Number:	732-823-4122
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	No
c. Special regulations for product in certain 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: <input type="text" value="24"/> Months	
Initial shelf life at launch (if different):	<input type="text"/> Months

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AP
II. Brand Name:	Naropin
III. Generic Equivalent for Brand:	ropivacaine

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
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		ORDER INFORMATION	
Is the Product... Direct Ship Item	<input type="checkbox"/>	Unit of Sale	What is the NDC selling unit?
Legend Device?	No	<input checked="" type="checkbox"/> Bottle	25 Vials in one Carton. The Carton NDC No. is 55150-200-10
State Control?	No	<input checked="" type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
ARCOS reportable?	No	<input type="checkbox"/> Ampule	Minimum order quantity? Yes
Co-Licensed?	No	<input type="checkbox"/> Glass	If Yes, how many of which package type?
Controlled Substance?	No	<input type="checkbox"/> Tube	<input type="text" value="8"/> Each
Schedule No.?		<input type="checkbox"/> Vial Liquid Sgl	<input type="text" value="1"/> Inner/ Carton/ Pack
(incl. N for non-narcotic)		<input type="checkbox"/> Vial Liquid Multi	<input type="text" value="1"/> Case
Controlled Substance Code:		<input type="checkbox"/> Vial Powder Sgl	
Hazardous Material/Cytotoxic Agent?	No	<input type="checkbox"/> Vial Power Multi	
Is Item...		<input type="checkbox"/> Other: Write In	
If Unit Dose, is item bar coded to unit dose for hospital scanning?			
Is it reverse numbered?			

ITEM AND PACKING INFORMATION							
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:	
		Depth	Height	Width:			
Box/ Carton:	1.59705 (Carton contains 25 Vials)	3.555 (Carton contains 25 Vials)	2.4405 (Carton contains 25 Vials)	3.555 (Carton contains 25 Vials)		Carton (25 Vials)	
Case:	12.464	11.811	6.2992	11.811		(Two 3 Ply Cases)	
Pallet:	300.412 (For Sea)	48	42.7105 (For Sea)	40		For Sea (72 Shippers or 576 Ndc's)	
UPC:	Case: 1229.536 (For Sea)	Carton: 355150200108					

WHOLESALE USE ONLY:		PHARMACY ORDER / BILL UNIT		Other Product Information	
Vendor #:		Rec. sell unit to customer?		Size/Strength/Form:	
Whsl. Code #:		(Write-in, e.g. 1 Vial)		Product Shape:	
Fineline Code:		Rx billing unit to pharmacy:		Product Color:	
		<input type="checkbox"/> Each		Product Imprint:	
		<input type="checkbox"/> Gram			
		<input type="checkbox"/> Milliliter			

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
	\$275.00	
As of date: <input type="text" value="10/28/2016"/>		

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:



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WHOLESALE USE ONLY:		COST INFORMATION	
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