



Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: New Item Final VersionDate:

PRODUCT INFORMATION	
Company Name:	Auromedics Pharma LLC
Application:	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	204702
DUNS:	968961354
Proprietary Name (If Applicable) and Established Name:	Palonosetron Hydrochloride Injection 0.25 mg per 5 mL(0.05 mg / mL) (MONO)
Selling Unit NDC:	55150-186-05
Individual Unit NDC:	55150-186-05
UPC:	355150186051
CVX Code:	
MVX Code:	
Description:	Palonosetron Hydrochloride Injection 0.25 mg per 5 mL(0.05 mg / mL) (MONO)
Active Ingredient(s):	
URL for Additional Product Information:	www.auromedics.com
Address:	279 Princeton-Hightstown Road
City:	East Windsor
Key Contact:	
Phone Number:	888-238-7880
Product Therapeutic Classification:	Antiemetic

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)	Store at 20° to 25°C (68° to 77°F).
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:	888-238-7880
Group E-mail:	pvg@aurobindousa.com
c. Special regulations for product in any states?	No
Special returns requirements for this product?	No
d. Store product (unit of sale) upright?	Yes
Protect product (unit of sale) from light?	No
e. Shelf life:	
Initial shelf life at launch (if different):	<input type="text" value="24"/> Months

ADDITIONAL PRODUCT INFORMATION	
Is the Product... a legend device?	No
reverse numbered?	No
co-licensed?	No
Is the Product... Direct-Ship Only	<input type="checkbox"/>
Is the Product... Direct-Ship Only	<input type="checkbox"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/>
If Unit Dose NDC, indicate NDC here:	<input type="text"/>
Country of Origin	India
Is this product covered under the Trade Agreements Act (TAA)?	No

PRODUCT DESCRIPTION INFORMATION	
Size:	Mono Vial
Strength:	0.25 mg per 5 mL(0.05 mg / mL) (MONO)
Dosage Form:	Liquid
Product Shape:	
Product Color:	
Product Imprint:	

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input type="checkbox"/> Bottle	55150-186-05
<input checked="" type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<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 Powder Multi	
<input type="checkbox"/> Other: Write In	
	Minimum order quantity? Yes
	If Yes, how many of which package type?
	<input type="text" value="1"/> Each
	<input type="text" value="1"/> Inner/Carton/Pack
	<input type="text" value="1"/> Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AP
II. Generic Equivalent to What Brand?:	Aloxi
<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"/> (Write-in, e.g. 1 Vial)	<input type="text" value="1"/> Each
	<input type="text" value="1"/> Gram
	<input type="text" value="1"/> 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:	035515000005
If Yes, was original product purchased direct from mfr?	<input type="checkbox"/>
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Box/Carton/Bundle/Inner Pack:	0.077	1.42	2.36	1.26	4.222512	1
Case:	3.168	9.29	3.19	8.7	257.82537	36
Pallet:	15.007	18.701	8.268	10.433	1613.14908	144
UPC:	708.35	48	46.34	40	88972.8	6480
Case:						
Carton:						

GTIN PRODUCT INFORMATION						
Serialized?	Level	Item	Saleable Unit	Quantity	GTIN-14	If not, when?
<input checked="" type="checkbox"/>	Item		<input checked="" type="checkbox"/>	1	00355150186051	
<input checked="" type="checkbox"/>	Box/Carton/Bundle/Inner Pack			36	30355150186052	
<input checked="" type="checkbox"/>	Case			144	50355150186056	
<input checked="" type="checkbox"/>	Pallet			6480	70355150186050	

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$227.00	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:	1/1/2019		

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? | |
| Is the product a CA Prop 65 carcinogen? | No |
| Is the product a CA Prop 65 reproductive toxicant? | No |
| Does the product label bear a CA Prop 65 warning? | No |
| c. Contact Hazard? | No |
| d. Does this product require special clean-up instructions?
(If yes, attach SDS with special instructions.) | No |
| e. Does the product contain DEHP? | No |
| Is this product regulated for shipment by DOT or IATA?
(if yes, answer a-e below and provide SDS) | No |

- | | |
|-----------------------------|--|
| a. UN/Identification Number | |
| b. Proper Shipping Name | |
| c. DOT Hazard Class | |
| d. Packing Group | |
| e. Inhalation Hazard? | |

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

- Passenger
 Cargo
 Passenger & Cargo

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#

ADD'L STORAGE INFORMATION

Is the Product...

- | | |
|---|----|
| Controlled Substance? | No |
| Controlled by State(s)? | No |
| ARCOS Reportable? | No |
| Schedule No. (inc. N for non-narcotic) | |
| Controlled Substance Code | |
| Listed Chemical (List I or II) | No |
| If yes, indicate which: | |
| Is it a scheduled listed chemical product?: | No |

CLASS OF TRADE RESTRICTION:

- No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes
- Restricted to retail pharmacy only:
- Restricted to hospital, clinics, and physician offices only:
- Restricted from US territories? (explain in comments)
- Comments:

SDS Hazard Classification

- | | |
|--|---|
| <input type="checkbox"/> Organic
<input type="checkbox"/> Inorganic
<input type="checkbox"/> Steroid/Androgen

<input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input style="width: 100px;" type="text"/> | <input type="checkbox"/> Corrosive
<input type="checkbox"/> Oxidizer
<input type="checkbox"/> Contact Hazard

Is the product a NIOSH hazardous drug? <input style="width: 100px;" type="text"/>
If yes, indicate which: <input style="width: 100px;" type="text"/> |
|--|---|

Hazardous Waste Identification

EPA Hazardous Waste Code:

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?)

REMS:

REMS Program Manager Name: <input style="width: 100px;" type="text"/>	Phone: <input style="width: 100px;" type="text"/>
Supplier Manages REMS registry exclusively: <input style="width: 100px;" type="text"/>	
Wholesale distributor support: <input style="width: 100px;" type="text"/>	
Provider Name: <input style="width: 100px;" type="text"/>	DEA #: <input style="width: 100px;" type="text"/>
Site Enrollment Number assigned by Supplier: <input style="width: 100px;" type="text"/>	PCPDP #: <input style="width: 100px;" type="text"/>
	NPI #: <input style="width: 100px;" type="text"/>

Comments:

Registry:

Registry Program Contact Name: Phone:

Comments:

RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

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:

MISCELLANEOUS NOTES and/or Image of Product Barcode:

