



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

Version 2021

Introduction Type: New Item

Final Version

Date:

PRODUCT INFORMATION	
Company Name:	AuroMedics Pharma LLC
Application:	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	211864
Medical Device Class, if applicable:	
DUNS:	968961354
Proprietary Name (If Applicable) and Established Name:	
Selling Unit NDC:	55150-316-25
Unit of Use NDC:	55150-316-01
UPC:	355150316250
UDI	
CVX Code:	
MVX Code:	
Description:	Isoproterenol HCl Injection, USP 0.2 mg per 1 mL(0.2 mg per mL) 25 x 1 mL Ampuls
Active Ingredient(s):	ISOPROTERENOL HYDROCHLORIDE
URL for Additional Product Information:	
Address:	279 Princeton-Hightstown Road
City:	East Windsor
State:	NJ
Zip:	08520
Key Contact:	
Phone Number:	888-238-7880
Fax:	732-355-9449
Product Therapeutic Classification:	Nonselective beta-adrenergic agonist

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
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)	<input type="text" value="Store at 20° to 25°C (68° to 77°F)."/>
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"/>
b. Contact for temperature excursion questions:	
Name:	<input type="text" value="Steve Lucas"/>
Number:	<input type="text" value="732-823-4122"/>
Group E-mail:	<input type="text" value="slucas@aurobindo.com"/>
c. Special regulations for product in any states?	
Special returns requirements for this product?	<input type="checkbox"/> No
d. Store product (unit of sale) upright?	<input type="checkbox"/> No
Protect product (unit of sale) from light?	<input type="checkbox"/> No
e. Shelf life:	<input type="text" value="24"/> Months
Initial shelf life at launch (if different):	<input type="text"/>

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is?		Is the Product...	<input type="checkbox"/> Direct-Ship Only
a legend device?	<input type="checkbox"/> No	Is the Product...	<input type="checkbox"/> Neither
if yes, enter class #	<input type="text"/>	Orphan Drug Status	<input type="checkbox"/>
a product kit?	<input type="checkbox"/> No	FDA Approval Status	<input type="text"/>
if yes, list NDCs of component parts	<input type="text"/>	Allergens Present	<input type="text"/>
reverse numbered?	<input type="checkbox"/> No	Country of Origin	<input type="text" value="India"/>
co-licensed?	<input type="checkbox"/> No	Is this product covered under the Trade Agreements Act (TAA)?	<input type="checkbox"/> No
latex-free?	<input type="checkbox"/> Yes	Size:	<input type="text" value="25 x 1 mL Ampuls"/>
preservative-free?	<input type="checkbox"/> Yes	Strength:	<input type="text" value="0.2 mg per 1 mL"/>
correctional institution block?	<input type="checkbox"/> No	Dosage Form:	<input type="text" value="Liquid"/>
opioid?	<input type="checkbox"/> No	Product Shape:	<input type="text" value="Ampoules"/>
Cannabinoid?	<input type="checkbox"/> No	Product Color:	<input type="text"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/>	Product Imprint:	<input type="text"/>
If Unit Dose, indicate NDC here:	<input type="text"/>		

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input type="checkbox"/> Bottle	<input type="text" value="1 box of 25 ampoules"/>
<input checked="" type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	Minimum order quantity?
<input type="checkbox"/> Glass	<input type="checkbox"/> Yes
<input type="checkbox"/> Tube	If Yes, how many of which package type?
<input type="checkbox"/> Vial Liquid Sgl	<input type="text" value="1"/> Each
<input type="checkbox"/> Vial Liquid Multi	<input type="text"/>
<input type="checkbox"/> Vial Powder Sgl	<input type="text"/>
<input type="checkbox"/> Vial Powder Multi	<input type="text"/>
<input type="checkbox"/> Other: Write In	<input type="text"/>

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

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
<input type="text" value="25 x 1 mL Ampuls Carton"/>	<input checked="" type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Gram
	<input checked="" type="checkbox"/> Milliliter

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

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Depth	Width	Height	Volume (Cube)	Saleable # Pieces
Item/Each:	0.426	3.35	3.35	3.15	35.350875	25
Box/Carton/Bundle/Inner Pack:						
Case:	6.921	11.61	8.26	9.05	867.88233	12
Pallet:	656.03	48	40	50.28	96537.6	90

GTIN AND HIBCC PRODUCT INFORMATION				
Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	25		00355150316250	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input type="checkbox"/> Case	12		50355150316255	
<input type="checkbox"/> Pallet	90		70355150316259	

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	<input type="text"/>
Invoice Cost (WAC) (\$)	\$11,250.00	Whsl. Code #:	<input type="text"/>
As of date:	11/3/2021	Fineline Code:	<input type="text"/>

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:

D.Venkata Surender Reddy



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

Version 2021

Introduction Type: New Item

Final Version

Date: 9/9/2021

PRODUCT INFORMATION	
Company Name:	AuroMedics Pharma LLC
Application:	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	211864
Medical Device Class, if applicable:	
DUNS:	968961354
Proprietary Name (If Applicable) and Established Name:	
Selling Unit NDC:	55150-317-10
Unit of Use NDC:	55150-317-01
UPC:	355150317103
UDI	
CVX Code:	
MVX Code:	
Description:	Isoproterenol HCl Injection, USP 1 mg per 5 mL (0.2 mg / mL) 10 x 5 mL Ampuls
Active Ingredient(s):	ISOPROTERENOL HYDROCHLORIDE
URL for Additional Product Information:	
Address:	279 Princeton-Hightstown Road
City:	East Windsor
State:	NJ
Address 2:	
Zip:	08520
Key Contact:	
Phone Number:	888-238-7880
Fax:	732-355-9449
Product Therapeutic Classification:	Nonselective beta-adrenergic agonist

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).
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"/>
b. Contact for temperature excursion questions:	
Name:	Steve Lucas
Number:	732-823-4122
Group E-mail:	slucas@aurobindo.com
c. Special regulations for product in any states?	
Special returns requirements for this product?	<input type="checkbox"/> No
d. Store product (unit of sale) upright?	<input type="checkbox"/> No
Protect product (unit of sale) from light?	<input type="checkbox"/> No
e. Shelf life:	24 Months
Initial shelf life at launch (if different):	Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is?		Is the Product...	Direct-Ship Only
a legend device?	<input type="checkbox"/> No	Is the Product...	Neither
if yes, enter class #		Orphan Drug Status	
a product kit?	<input type="checkbox"/> No	FDA Approval Status	
if yes, list NDCs of component parts		Allergens Present	
reverse numbered?	<input type="checkbox"/> No	Country of Origin	India
co-licensed?	<input type="checkbox"/> No	Is this product covered under the Trade Agreements Act (TAA)?	<input type="checkbox"/> No
latex-free?	<input type="checkbox"/> Yes	Size:	10 x 5 mL Ampuls
preservative-free?	<input type="checkbox"/> Yes	Strength:	1 mg per 5 mL
correctional institution block?	<input type="checkbox"/> No	Dosage Form:	Liquid
opioid?	<input type="checkbox"/> No	Product Shape:	Ampoules
Cannabinoid?	<input type="checkbox"/> No	Product Color:	
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/>	Product Imprint:	
If Unit Dose, indicate NDC here:			

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

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AP
II. Generic Equivalent to What Brand?:	Isuprel Injection
<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:
10 x 5 mL Ampuls Carton	<input checked="" type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Gram
	<input checked="" type="checkbox"/> Milliliter

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

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.315	7.56	0.98	3.62	26.819856	10
Box/Carton/Bundle/Inner Pack:						
Case:	35.752	16.73	13.97	17.71	4139.1476	96
Pallet:	676.61	48	40	58.15	111648	18

GTIN AND HIBCC PRODUCT INFORMATION				
Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	10		00355150317103	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	96		50355150317108	
<input type="checkbox"/> Pallet	18		70355150317102	

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$5,450.00	Whsl. Code #:	
As of date:		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:

D.Venkata Surender Reddy