



Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: New Item Final VersionDate:

PRODUCT INFORMATION	
Company Name:	Auromedics Pharma LLC
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	212174
DUNS:	968961354
Proprietary Name (if Applicable) and Established Name:	Furosemide Injection, USP 20 mg per 2mL (10 mg/mL)
Selling Unit NDC:	55150-322-25
UDI	Individual Unit NDC: 55150-322-25
	CVX Code: <input type="text"/>
	UPC: 355150322251
	MVX Code: <input type="text"/>
Description:	Furosemide Injection, USP 20 mg per 2mL (10 mg/mL)
Active Ingredient(s):	Furosemide
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:	Diuretics, loop

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°)
Other Temperature Range Requirement (write in)	<input type="text"/>
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"/>
b. Contact for temperature excursion questions:	
Name:	Steve Lucas
Number:	888-238-7880
Group E-mail:	pvg@aurobindowsa.com
c. Special regulations for product in any 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:	
Initial shelf life at launch (if different):	<input type="text" value="24"/> Months

ADDITIONAL PRODUCT INFORMATION	
Is the Product... a legend device?	<input type="text" value="No"/>
reverse numbered?	<input type="text" value="No"/>
co-licensed?	<input type="text" value="No"/>
Is the Product... Direct-Ship Only	<input type="text"/>
Is the Product... Neither	<input type="text"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text"/>
If Unit Dose NDC, indicate NDC here:	<input type="text"/>
Country of Origin	<input type="text" value="India"/>
Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="No"/>

PRODUCT DESCRIPTION INFORMATION	
Size:	25 x 2 mL Single dose vials
Strength:	20 mg per 2mL (10 mg/mL)
Dosage Form:	Liquid
Product Shape:	<input type="text"/>
Product Color:	<input type="text"/>
Product Imprint:	<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 vials"/>
<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? <input type="text" value="Yes"/>
	If Yes, how many of which package type?
	<input type="text"/> Each
	<input type="text"/> Inner/ Carton/Pack
	<input type="text" value="1"/> Case

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

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

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

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:	0.847	3.54	1.97	3.54	24.687252	25 vials / 1 pack
Box/Carton/Bundle/Inner Pack:	10.604	11.1	4.72	7.48	391.89216	300 vials / 12 packs
Case:	44.421	15.945	11.02	12.402	2179.20379	1200 vials / 48 packs
Pallet:	1232.384	48	38.07	40	73094.4	32400 vials / 3,456 packs
UPC:	Case:	50355150322256				
	Carton:	00355150322251				

GTIN PRODUCT INFORMATION						
Serialized?	Level	Saleable Unit		Quantity	GTIN-14	
		Item	Unit			
<input checked="" type="checkbox"/>	Box/Carton/Bundle/Inner Pack	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	2D	00355150322251	is in one carton
<input checked="" type="checkbox"/>	Case	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	2D	30355150322252	is in one e flut
<input checked="" type="checkbox"/>	Pallet	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	2D	50355150322256	boxes in one s
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	2D	70355150322250	bers in one pa
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	2D		
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	2D		
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	2D		
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	2D		
<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	2D		

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost	<input type="text"/>	Vendor #:	<input type="text"/>
Invoice Cost (WAC) (\$)	\$52.50	Whsl. Code #:	<input type="text"/>
Federal Excise Tax Per Unit of Sale	<input type="text"/>	Fineline Code:	<input type="text"/>
As of date:	<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:



Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: New Item Final VersionDate:

PRODUCT INFORMATION	
Company Name:	Auromedics Pharma LLC
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	212174
DUNS:	968961354
Proprietary Name (if Applicable) and Established Name:	Furosemide Injection, USP 40 mg per 4mL (10 mg/mL)
Selling Unit NDC:	55150-323-25
UDI	Individual Unit NDC: 55150-323-25
	CVX Code:
	UPC: 355150323258
	MVX Code:
Description:	Furosemide Injection, USP 40 mg per 4mL (10 mg/mL)
Active Ingredient(s):	Furosemide
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:	Diuretics, loop

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°)"/> Other Temperature Range Requirement (write in): <input type="text" value="Store at 20° to 25°C (68° to 77°F)"/>
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"/>
b. Contact for temperature excursion questions:	Name: <input type="text" value="Steve Lucas"/> Number: <input type="text" value="888-238-7880"/> Group E-mail: <input type="text" value="pvg@aurobindousa.com"/>
c. Special regulations for product in any 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" value=""/> Months

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

PRODUCT DESCRIPTION INFORMATION	
Size:	<input type="text" value="25 x 4 mL Single dose vials"/>
Strength:	<input type="text" value="40 mg per 4mL (10 mg/mL)"/>
Dosage Form:	<input type="text" value="Liquid"/>
Product Shape:	<input type="text" value=""/>
Product Color:	<input type="text" value=""/>
Product Imprint:	<input type="text" value=""/>

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input type="checkbox"/> Bottle	<input type="text" value="1 box of 25 vials"/>
<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? <input type="text" value="Yes"/>
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	If Yes, how many of which package type?
<input type="checkbox"/> Vial Liquid Multi	<input type="text" value=""/> Each
<input type="checkbox"/> Vial Powder Sgl	<input type="text" value=""/> Inner/ Carton/ Pack
<input type="checkbox"/> Vial Power Multi	<input type="text" value="1"/> Case
<input type="checkbox"/> Other: Write In	

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

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

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

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Depth	Height	Width	Volume (Cube)	# Pieces:
Item:	1.1771	5.31	2.36	5.31	66.542796	5 vials / 1 pack
Box/ Carton/ Bundle/ Inner Pack:	1.1771	5.31	2.36	5.31	66.542796	5 vials / 1 pack
Case:	10.694	11.811	6.299	11.811	878.708743	200 vials / 8 packs
Pallet:	802.971	48	42.8	40	82176	14400 vials / 576 packs
UPC:	Case:	50355150323253				
	Carton:	00355150323258				

GTIN PRODUCT INFORMATION				
Serialized?	Level	Saleable Unit	Quantity	GTIN-14
<input checked="" type="checkbox"/>	Item	<input checked="" type="checkbox"/>	2D	5 in one carton 00355150323258
<input checked="" type="checkbox"/>	Box/ Carton/ Bundle/ Inner Pack	<input checked="" type="checkbox"/>	2D	1 in 1 e flute 30355150323259
<input checked="" type="checkbox"/>	Case	<input checked="" type="checkbox"/>	2D	boxes in one s 50355150323253
<input checked="" type="checkbox"/>	Pallet	<input checked="" type="checkbox"/>	2D	bers in one pa 70355150323257
			2D	
			2D	
			2D	
			2D	

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost	<input type="text" value=""/>	Vendor #:	<input type="text" value=""/>
Invoice Cost (WAC) (\$)	<input type="text" value="\$70.00"/>	Whsl. Code #:	<input type="text" value=""/>
Federal Excise Tax Per Unit of Sale	<input type="text" value=""/>	Fineline Code:	<input type="text" value=""/>
As of date:	<input type="text" value=""/>		



Standard Pharmaceutical Product Information (Rx Product Only)

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):	212174				
DUNS:	968961354				
Proprietary Name (if Applicable) and Established Name:	Furosemide Injection, USP 100 mg per 10mL (10 mg/mL)				
Selling Unit NDC:	55150-324-25	Individual Unit NDC:	55150-324-25	UPC:	355150324255
UDI		CVX Code:		MVX Code:	
Description:	Furosemide Injection, USP 100 mg per 10mL (10 mg/mL)				
Active Ingredient(s):	Furosemide				
URL for Additional Product Information:	www.auromedics.com				
Address:	279 Princeton-Hightstown Road		Address 2:		
City:	East Windsor		State:	NJ	
Key Contact:		Email:		Zip:	08520
Phone Number:	888-238-7880		Fax:	732-355-9449	
Product Therapeutic Classification:					

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°)
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@auromedics.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	
Is the Product... a legend device?	No
reverse numbered?	No
co-licensed?	No
Is the Product... Direct-Ship Only	
Is the Product...	
If Unit Dose, is item bar coded to unit dose for hospital scanning?	
If Unit Dose NDC, indicate NDC here:	
Country of Origin	India
Is this product covered under the Trade Agreements Act (TAA)?	No

PRODUCT DESCRIPTION INFORMATION	
Size:	25 x 10 mL Single Dose Vials.
Strength:	100 mg per 10mL (10 mg/mL)
Dosage Form:	Liquid
Product Shape:	
Product Color:	
Product Imprint:	

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 box of 25 vials
<input 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?
	Each
	Inner/ Carton/ Pack
	1 Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AP
II. Generic Equivalent to What Brand?:	Furosemide 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:
25 s vials carton	<input checked="" type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Gram
	<input type="checkbox"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION		
Does supplier meet DSCSA definition of manufacturer?	Yes	GLN:
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	If yes, attach documentation from FDA.
Has FDA granted a waiver/exception/exemption for product?	No	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:	1.5071	5.31	2.36	5.31	66.542796	5 vials / 1 pack
Box/ Carton/ Bundle/ Inner Pack:	1.5071	5.31	2.36	5.31	66.542796	5 vials / 1 pack
Case:	13.334	11.811	6.299	11.811	878.708743	200 vials / 8 packs
Pallet:	993.051	48	42.8	40	82176	14400 vials / 576 packs
UPC:	Case:	50355150324250				
	Carton:	00355150324255				

GTIN PRODUCT INFORMATION						
Serialized?	Level	Saleable Unit		Quantity	GTIN-14	Description
		Item	Unit			
<input checked="" type="checkbox"/>	Box/ Carton/ Bundle/ Inner Pack	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	1	00355150324255	1 in 1 e flute
<input checked="" type="checkbox"/>	Case	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	8	30355150324256	boxes in one s
<input checked="" type="checkbox"/>	Pallet	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	80	50355150324250	boxes in one pa

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$80.00	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:			