



# 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):	211816
DUNS:	968961354
Proprietary Name (if Applicable) and Established Name:	Chlorpromazine Hydrochloride Injection, USP 25 mg/mL
Selling Unit NDC:	55150-318-25
Individual Unit NDC:	55150-318-01
UPC:	355150318254
CVX Code:	
MVX Code:	
Description:	Chlorpromazine Hydrochloride Injection, USP 25 mg/mL (25 x 2 mL Ampoules) 1 mL Fill Volume
Active Ingredient(s):	Chlorpromazine Hydrochloride
URL for Additional Product Information:	
Address:	279 Princeton-Hightstown Road
City:	East Windsor
Key Contact:	
Phone Number:	888-238-7880
Product Therapeutic Classification:	Antipsychotics, Antiemetics

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	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) [see]
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:	Steve Lucas
Name:	732-823-4122
Number:	slucas@aurobindousa.com
Group E-mail:	
c. Special regulations for product in any states?	No
Special returns requirements for this product?	No
d. Store product (unit of sale) upright?	No
Protect product (unit of sale) from light?	No
e. Shelf life:	24 Months
Initial shelf life at launch (if different):	

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... Neither	
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 2 mL Ampoules
Strength:	25 mg/mL (25 x 2 mL Ampoules) 1 mL Fill Volume
Dosage Form:	LIQUID
Product Shape:	Ampoule Pack
Product Color:	
Product Imprint:	

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

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AP
II. Generic Equivalent to What Brand?:	Thorazine® Injection, 25 mg/mL (GlaxoSmithKline)
<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:
Multi Ampoules (25s) carton	<input checked="" type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	Gram
	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:	
If Yes, was original product purchased direct from mfr?	
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Depth	Height	Width	Volume (Cube)	# Pieces:
Item:	0.5504	3.43	3.15	3.43	37.059435	25 ampoules
Box/Carton/Bundle/Inner Pack:	3.9707	10.67	3.94	7.32	307.731336	of 25) 150 a
Case:	8.978	11.614	9.055	8.268	869.502318	s of 25) 300 a
Pallet:	1002.6936	48	58.15	40	111648	(1296 packs of 25) 32400
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION									
Serialized?	Yes	Level	Saleable Unit	Quantity	GTIN-14				
If not, when?		<input checked="" type="checkbox"/> Item	<input checked="" type="checkbox"/>	25	00355150318254				
Items aggregated?		<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack	<input checked="" type="checkbox"/>	150	30355150318255				
		<input checked="" type="checkbox"/> Case	<input checked="" type="checkbox"/>	300	50355150318259				
		<input checked="" type="checkbox"/> Pallet	<input checked="" type="checkbox"/>	32400	70355150318253				

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$722.25	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:			

**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

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? No  
 (If yes, attach SDS with special instructions.)

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)

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: No

Restricted to hospital, clinics, and physician offices only: No

Restricted from US territories? (explain in comments)

Comments:

SDS Hazard Classification	
<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer
<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard
<input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input type="text"/>	
Is the product a NIOSH hazardous drug? <span style="float: right;">No</span>	
If yes, indicate which: <input type="text"/>	

Hazardous Waste Identification	
EPA Hazardous Waste Code:	<input type="text"/>

REMS or REGISTRY RESTRICTIONS	
Is there a REMS on this product? <span style="float: right;">No</span>	
If Yes, is it managed with a pharmacy registry? <input type="text"/>	
Website URL: <input type="text"/>	
Comments / Details: (For example, iPledge program?) <input type="text"/>	
<b>REMS:</b> <span style="float: right;">No</span>	
REMS Program Manager Name: <input type="text"/>	Phone: <input type="text"/>
Supplier Manages REMS registry exclusively: <input type="text"/>	
Wholesale distributor support: <input type="text"/>	
Provider Name: <input type="text"/>	
Site Enrollment Number assigned by Supplier: <input type="text"/>	DEA #: <input type="text"/>
	PCPDP #: <input type="text"/>
	NPI #: <input type="text"/>

Comments: <input type="text"/>
<b>Registry:</b> <input type="text"/>
Registry Program Contact Name: <input type="text"/>
Phone: <input type="text"/>
Comments: <input type="text"/>

**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:**

**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="checkbox"/></p> <p>b. Autofax <input type="checkbox"/> Fax Number: <input type="text"/></p> <p>c. Fax <input type="checkbox"/> Fax Number: <input type="text"/></p> <p>d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/></p> <p>e. Supplier Web Site only <input type="checkbox"/> 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 #: Name: <input type="text"/> Phone: <input type="text"/></p>	<p><b>Purchase order daily receipt cut off time by supplier</b></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="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
<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 style="width: 100%; height: 80px;" type="text"/></p>	<p><b>Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <p><b>Priority Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="checkbox"/></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="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>
Class of Trade Restriction:	Return Instructions
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input style="width: 100%; height: 80px;" type="text"/></p>	<p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></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="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input style="width: 100%; height: 80px;" type="text"/></p>
Other Data Information Required to Process PO:	ADDITIONAL INFORMATION
<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>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>
Miscellaneous Notes:	
<input style="width: 100%; height: 100px;" type="text"/>	



# 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):	211816
DUNS:	968961354
Proprietary Name (if Applicable) and Established Name:	Chlorpromazine Hydrochloride Injection, USP 50 mg/2 mL
Selling Unit NDC:	55150-319-25
Individual Unit NDC:	55150-319-01
UPC:	355150319251
CVX Code:	
MVX Code:	
Description:	Chlorpromazine Hydrochloride Injection, USP 50 mg/2 mL (25 mg/mL) (25 x 2 mL Ampoules) 2 mL Fill Volume
Active Ingredient(s):	Chlorpromazine Hydrochloride
URL for Additional Product Information:	
Address:	279 Princeton-Hightstown Road
City:	East Windsor
Key Contact:	
Phone Number:	888-238-7880
Product Therapeutic Classification:	Antipsychotics, Antiemetics

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	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) [see]
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:	Steve Lucas
Name:	732-823-4122
Number:	slucas@aurobindousa.com
Group E-mail:	
c. Special regulations for product in any states?	No
Special returns requirements for this product?	No
d. Store product (unit of sale) upright?	No
Protect product (unit of sale) from light?	No
e. Shelf life:	24 Months
Initial shelf life at launch (if different):	

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... Neither	
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 2 mL Ampoules
Strength:	50 mg/2 mL (25 mg/mL) (25 x 2 mL Ampoules) 2 mL Fill Volume
Dosage Form:	LIQUID
Product Shape:	Ampoule Pack
Product Color:	
Product Imprint:	

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

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AP
II. Generic Equivalent to What Brand?:	Thorazine® Injection, 25 mg/mL (GlaxoSmithKline)
<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:
Multi Ampoules (25s) carton	<input checked="" type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	Gram
	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:	
If Yes, was original product purchased direct from mfr?	
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:	0.6054	3.43	3.15	3.43	37.059435	25 ampoules
Box/Carton/Bundle/Inner Pack:	4.3007	10.67	3.94	7.32	307.731336	of 25) 150 a
Case:	9.638	11.614	9.055	8.268	869.502318	s of 25) 300 a
Pallet:	1073.9736	48	58.15	40	111648	(1296 packs of 25) 32400
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION										
Serialized?	If not, when?	Items aggregated?	Level	Saleable Unit		Quantity	GTIN-14	2D	Linear	2D
				Item	Unit					
<input checked="" type="checkbox"/>			Box/Carton/Bundle/Inner Pack	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	25	00355150319251	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
			Case	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	150	30355150319252	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
			Pallet	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	300	50355150319256	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
						32400	70355150319250	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
								<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
								<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
								<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
								<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$827.50	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:			

**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)

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:  No

Restricted to hospital, clinics, and physician offices only:  No

Restricted from US territories? (explain in comments)

Comments:

**SDS Hazard Classification**

<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer
<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard

Aerosol Class; Identify NFPA Storage Level:

Is the product a NIOSH hazardous drug?  No  
 If yes, indicate which:

**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:**  No

REMS Program Manager Name:  Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:  
 Provider Name:   
 Site Enrollment Number assigned by Supplier:

DEA #:   
 PCPDP #:   
 NPI #:

Comments

**Registry:**

Registry Program Contact Name:  Phone:

Comments

**RETURN INSTRUCTIONS**

Contact tel. # if product received damaged:  888-238-7880

Is product returnable for credit:

URL/Link to returns policy:  <http://auromedics.com/policies/return-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:**

