



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: New Item

Final Version

Date:

PRODUCT INFORMATION				
Company Name:	AuroMedics Pharma LLC		Application:	ANDA
Application Number for NDA/ANDA/BLA, Med Device:	206128			
DUNS:	968961354			
Rx Product/Proprietary Name:	METHOCARBAMOL INJECTION USP 1,000 mg per 10 mL (100 mg/mL)			
NDC:	55150-223-10	UPC:	355150223107	
CVX Code:		MVX Code:		
Description:	METHOCARBAMOL INJECTION USP 1,000 mg per 10 mL (100 mg/mL)			
Active ingredients:				
URL for Additional Product Information:				
Address:	6 Wheeling Road	Address 2:		
City:	Dayton	State:	NJ	Zip: 08810
Key Contact:		Email:		
Phone Number:	888-238-7880	Fax:	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)
<input checked="" type="checkbox"/>	III. Cool – between 8 and 15 C (46° – 59° F)
<input 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"/>
Number:	<input type="text"/>
Is this product to be shipped to customers on ice?	<input type="text"/> No
Is this product to be shipped to customers on dry ice?	<input type="text"/> No

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

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

c. Special regulations for product in certain states?	<input type="text"/> No
Special returns requirements for this product?	<input type="text"/> No
d. Store product (unit of sale) upright?	<input type="text"/> No
Protect product (unit of sale) from light?	<input type="text"/> No
e. Shelf life:	<input type="text"/> 24 Months
Initial shelf life at launch (if different):	<input type="text"/> Months

ADDITIONAL PRODUCT INFORMATION		ORDER INFORMATION	
Is the Product... Direct Ship Item	<input type="text"/>	Unit of Sale	What is the NDC selling unit?
Legend Device?	<input type="text"/> No	<input checked="" type="checkbox"/> Bottle	25 Vials in one Carton. The Carton NDC No. is 55150-223-10.
State Control?	<input type="text"/> No	<input checked="" type="checkbox"/> Box/ Carton	(Write-in, e.g. 1 Box of 10 Vials)
ARCOS reportable?	<input type="text"/> No	<input type="checkbox"/> Ampule	Minimum order quantity? <input type="text"/> Yes
Co-Licensed?	<input type="text"/> No	<input type="checkbox"/> Glass	If Yes, how many of which package type?
Controlled Substance?	<input type="text"/> No	<input type="checkbox"/> Tube	<input type="text"/> Each
Schedule No. ? (incl. N for non-narcotic)	<input type="text"/>	<input type="checkbox"/> Vial Liquid Sgl	<input type="text"/> Inner/ Carton/ Pack
Controlled Substance Code:	<input type="text"/>	<input type="checkbox"/> Vial Liquid Multi	<input type="text"/> Case
Hazardous Material/Cytotoxic Agent?	<input type="text"/> No	<input type="checkbox"/> Vial Powder Sgl	
Is Item...	<input type="text"/>	<input type="checkbox"/> Vial Power Multi	
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text"/>	<input type="checkbox"/> Other: Write In	
Is it reverse numbered?	<input type="text"/>	<input type="checkbox"/>	

ITEM AND PACKING INFORMATION							
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:	
		Depth	Height	Width:			
Box/ Carton:	1.51910 (Carton)	5.31 (Carton contains 25)	2.36 (Carton contains 25)	5.31 (Carton contains 25)		Carton (25 Vials)	
Case:	13.434	11.811	6.299	11.811		Case (8 Cartons)	
Pallet:	1000.252 (For Sea)	48	43.03 (For Sea)	40		For Sea (72 Shippers or	
UPC:	Case:						
	Carton:	355150223107					

WHOLESALE USE ONLY:		PHARMACY ORDER / BILL UNIT		Other Product Information	
Vendor #:	<input type="text"/>	Rec. sell unit to customer?	<input type="text"/>		
Whsl. Code #:	<input type="text"/>	(Write-in, e.g. 1 Vial)	Product Shape:	<input type="text"/>	
Fineline Code:	<input type="text"/>	Rx billing unit to pharmacy:	Product Color:	<input type="text"/>	
		<input type="checkbox"/> Each	Product Imprint:	<input type="text"/>	
		<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
	\$1,450.00	
As of date: <input type="text"/> 7/7/2016		

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:



Standard Pharmaceutical Product Information (Page 2)

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

Carcinogen

Reproductive Toxicant

Both

Warning appears on label

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

Hazardous Waste Identification	
EPA Hazardous Waste Code:	

Is this product regulated for shipment by the DOT? No

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#

(if yes, answer a-d below and provide SDS)

a. DOT Hazard Class

b. UN/ID Number

c. Packing Group

d. Inhalation Hazard?

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

Passenger

Cargo

Passenger & Cargo

ADDITIONAL PRODUCT INFORMATION - Serialization					
Serialized?	Level	How?	RFID	GTIN-14	
<input type="checkbox"/>	Item	<input type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/>	10355150223104	
If not, when?	Box/Carton	<input type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/>	10355150223104	
Items aggregated to case?	Case	<input type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/>	50355150223102	
	Pallet	<input type="checkbox"/> 2D <input type="checkbox"/> Linear	<input type="checkbox"/>	70355150223106	

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?

If Yes, is it managed with a pharmacy registry?

Website URL:

Comments / Details: (For example, iPledge program?)

ADD'L STORAGE INFORMATION

Please check as appropriate for this product.

Organic Inorganic

Antineoplastic Steroid/Androgen

Corrosive Oxidizer

Aerosol Class; Identify NFPA Storage Level:

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?

Listed Chemical (List I or II) (Indicate or Write-in below):

Ephedrine

Pseudoephedrine

Phenylpropanolamine

Iodine (≥2.2%)

Other:

ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here:

CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices

Restricted to retail pharmacy only:

Restricted to hospital, clinics, and physician offices only:

Restricted from US territories? (explain in comments)

Comments:

MISCELLANEOUS NOTES and/or Image of Product Barcode:

