



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

Version 2021

Introduction Type: ☐ New Item☒ Final Version

Date: 5/1/2023

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
<b>Company Name:</b> Camber Pharmaceuticals, Inc. <b>Application:</b> ANDA				<b>a. Temperature – Indicate the USP temperature range for this product.</b>			
<b>Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):</b> 216446				Temperature Range: Cold – between 2 and 8 C (36° – 46° F)			
<b>Medical Device Class, if applicable:</b>				Other Temperature Range Requirement (write in):			
<b>DUNS:</b> 82-677-4775				Notes: Store refrigerated			
<b>Proprietary Name (If Applicable) and Established Name:</b> Promethazine Hydrochloride Suppositories, USP 25mg				Is this product to be shipped to customers on ice? <input type="checkbox"/> No			
<b>Selling Unit NDC:</b> 31722-041-31 <b>Unit of Use NDC:</b> <b>CVX Code:</b> <b>UPC:</b> 331722041317 <b>MXV Code:</b>				Is this product to be shipped to customers on dry ice? <input type="checkbox"/> No			
<b>Description:</b> Promethazine Hydrochloride Suppositories, USP 25mg				<b>b. Contact for temperature excursion questions:</b>			
<b>Active Ingredient(s):</b> Promethazine Hydrochloride				<b>Name:</b> Soma Raju			
<b>URL for Additional Product Information:</b> <a href="http://www.camberpharma.com">www.camberpharma.com</a>				<b>Number:</b> 732-529-0423			
<b>Address:</b> 1031 Centennial Ave (and) 800 Centennial Ave, Suite 1				<b>Group E-mail:</b> <a href="mailto:somaraju@heterousa.com">somaraju@heterousa.com</a>			
<b>City:</b> Piscataway				<b>c. Special regulations for product in any states?</b>			
<b>Key Contact:</b> Customer Service				Special returns requirements for this product? <input type="checkbox"/> No			
<b>Phone Number:</b> 1-866-827-3647				<b>d. Store product (unit of sale) upright?</b>			
<b>Product Therapeutic Classification:</b> Antihistamine, 1st Generation Antiemetic Agent				Protect product (unit of sale) from light? <input type="checkbox"/> No			
<b>Address 2:</b>				<b>e. Shelf life:</b>			
<b>State:</b> NJ <b>Zip:</b> 08854				Initial shelf life at launch (if different): <input type="checkbox"/> 24 Months			
<b>Email:</b> <a href="mailto:customerservice@camberpharma.com">customerservice@camberpharma.com</a>							
<b>Fax:</b> 732-562-8788							
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
<b>The product is?</b>				<b>Size:</b> 12ct			
<b>a legend device?</b> <input type="checkbox"/> No				<b>Strength:</b> 25mg			
<b>if yes, enter class #</b>				<b>Dosage Form:</b> Suppository			
<b>a product kit?</b> <input type="checkbox"/> No				<b>Product Shape:</b> Bullet shaped wrapped in an Alu/PE shell			
<b>if yes, list NDCs of component parts</b>				<b>Product Color:</b> White to off white			
<b>reverse numbered?</b> <input type="checkbox"/> No				<b>Product Imprint:</b> N/A			
<b>co-licensed?</b> <input type="checkbox"/> No							
<b>latex-free?</b> <input type="checkbox"/> Yes							
<b>preservative-free?</b> <input type="checkbox"/> Yes							
<b>correctional institution block?</b> <input type="checkbox"/> No							
<b>opioid?</b> <input type="checkbox"/> No							
<b>Cannabinoid?</b> <input type="checkbox"/> No							
<b>If Unit Dose, is item bar coded to unit dose for hospital scanning?</b> <input type="checkbox"/> No							
<b>If Unit Dose, indicate NDC here:</b> 31722-041-32							
<b>Is the Product...</b> <input type="checkbox"/> Direct-Ship Only							
<b>Is the Product...</b> <input type="checkbox"/> Unit Dose							
<b>Orphan Drug Status</b>							
<b>FDA Approval Status</b>							
<b>Allergens Present</b>							
<b>Animal Products</b>							
<b>Country of Origin</b> India							
<b>Is this product covered under the Trade Agreements Act (TAA)?</b> <input type="checkbox"/> No							
FOR GENERIC DRUG PRODUCTS							
<b>I. Orange Book Rating:</b> AB <input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable							
<b>II. Generic Equivalent to What Brand?:</b> Phenergan Suppositories							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
<b>Does supplier meet DSCSA definition of manufacturer?</b> <input type="checkbox"/> Yes <b>GLN:</b> 00331722000000							
<b>Is product exempt from DSCSA?</b> <input type="checkbox"/> No <b>GCP:</b>							
<b>If yes, select exemption:</b>							
<b>Other exemption - Write in:</b>							
<b>Is product repackaged?</b> <input type="checkbox"/> No <b>If yes, was original product purchased direct from mfr?</b> <input type="checkbox"/>							
<b>Is product sold by manufacturer's exclusive distributor?</b> <input type="checkbox"/> Yes <b>Provide source manufacturer for repackaged product</b>							
<b>Has FDA granted waiver/exception/exemption for product?</b> <input type="checkbox"/> No							
<b>If yes, attach documentation from FDA.</b>							
GTIN AND HIBCC PRODUCT INFORMATION							
<b>Saleable Unit of Measure</b>							
<input checked="" type="checkbox"/> Item/Each							
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack							
<input checked="" type="checkbox"/> Case							
<input type="checkbox"/> Pallet							
<b>Saleable Quantity</b>							
1							
24							
<b>HIBCC</b>							
<b>GTIN-14</b>							
00331722041317							
20331722041311							
<b>Unit of Use GTIN-14</b>							
ITEM AND PACKING INFORMATION							
<b>Weight Lbs.</b> <b>Dimensions (US msmts.)</b> <b>Volume (Cube)</b> <b>Saleable # Pieces</b>							
<b>Depth</b> <b>Width</b> <b>Height</b>							
<b>Item/Each:</b> 0.2 4.72 1 2.36 1							
<b>Box/ Carton/ Bundle/ Inner Pack:</b>							
<b>Case:</b> 5.5 12.4 10.03 3.15 24							
<b>Pallet:</b>							
COST INFORMATION				WHOLESALE USE ONLY:			
<b>Regular Cost</b>				<b>Vendor #:</b>			
<b>Invoice Cost (WAC) (\$)</b> \$80.00				<b>Whsl. Code #:</b>			
<b>As of date:</b>				<b>Fineline Code:</b>			

\*Please provide any additional information on page 2.

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

See new p. 3 for Designated Drop Ship Only.

Signature:



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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION			
<b>Is this product (check all that apply):</b>			
a. Cytotoxic?	<input type="text"/>	<input type="text"/>	
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	<input type="text"/>	<input type="text"/>	
Is the product a CA Prop 65 carcinogen?	<input type="text"/>	<input type="text"/>	
Is the product a CA Prop 65 reproductive toxicant?	<input type="text"/>	<input type="text"/>	
Does the product label bear a CA Prop 65 warning?	<input type="text"/>	<input type="text"/>	
c. Contact Hazard?	<input type="text"/>	<input type="text"/>	
d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)	<input type="text"/>	<input type="text"/>	
e. Does the product contain DEHP?	<input type="text"/>	<input type="text"/>	
<b>Is this product regulated for shipment by DOT?</b> (if yes, answer a-e below and provide SDS)		<input type="text"/>	
a. UN/Identification Number	<input type="text"/>	<input type="text"/>	
b. Proper Shipping Name	<input type="text"/>	<input type="text"/>	
c. DOT Hazard Class	<input type="text"/>	<input type="text"/>	
d. Packing Group	<input type="text"/>	<input type="text"/>	
e. Inhalation Hazard?	<input type="text"/>	<input type="text"/>	
<b>Is this product regulated for shipment by IATA?</b> (if yes, answer a-e below and provide SDS)		<input type="text"/>	
a. UN/Identification Number	<input type="text"/>	<input type="text"/>	
b. Proper Shipping Name	<input type="text"/>	<input type="text"/>	
c. DOT Hazard Class	<input type="text"/>	<input type="text"/>	
d. Packing Group	<input type="text"/>	<input type="text"/>	
e. Inhalation Hazard?	<input type="text"/>	<input type="text"/>	
<b>Is the product restricted for air shipment? If so, indicate restriction:</b>		<input type="text"/>	
<input type="checkbox"/> Passenger	<input type="text"/>	<input type="text"/>	
<input type="checkbox"/> Cargo	<input type="text"/>	<input type="text"/>	
<input type="checkbox"/> Passenger & Cargo	<input type="text"/>	<input type="text"/>	
<b>Is this a reportable quantity?</b> <input type="text"/>		<input type="text"/>	
RQ Threshold: <input type="text"/>		<input type="text"/>	
<b>Is this a marine pollutant?</b> <input type="text"/>		<input type="text"/>	
<b>Is this product shipped utilizing an authorized DOT exception or Special Permit?</b>		<input type="text"/>	
<input type="checkbox"/> No (if yes, identify method below)		<input type="text"/>	
<input type="checkbox"/> Limited Quantity	<input type="text"/>	<input type="text"/>	
<input type="checkbox"/> Consumer Commodity, ORM-D	<input type="text"/>	<input type="text"/>	
<input type="checkbox"/> Small Quantity (49 CFR 173.4)	<input type="text"/>	<input type="text"/>	
<input type="checkbox"/> Special Permit; DOT-SP	<input type="text"/>	<input type="text"/>	
<input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101);	<input type="text"/>	<input type="text"/>	
SP#	<input type="text"/>	<input type="text"/>	
<b>ADD'L STORAGE INFORMATION</b>			
<b>Is the Product...</b>			
Controlled Substance?	<input type="text"/>	Controlled Substance Code	<input type="text"/>
Controlled by State(s)?	<input type="text"/>	Listed Chemical (List I or II)	<input type="text"/>
ARCOS Reportable?	<input type="text"/>	If yes, indicate which:	<input type="text"/>
Schedule No.	<input type="text"/>	Is it a scheduled listed chemical product?:	<input type="text"/>
<b>CLASS OF TRADE RESTRICTION:</b>			
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices		<input type="text"/>	
Restricted to retail pharmacy only:		<input type="text"/>	
Restricted to hospital, clinics, and physician offices only:		<input type="text"/>	
Restricted from US territories? (explain in comments)		<input type="text"/>	
Comments:		<input type="text"/>	
<b>MISCELLANEOUS NOTES and/or Image of Product Barcode:</b>			
<input type="text"/>			

SDS Hazard Classification	
<input checked="" type="checkbox"/> Organic	<input type="text"/>
<input type="checkbox"/> Inorganic	<input type="text"/>
<input type="checkbox"/> Steroid/Androgen	<input type="text"/>
<input type="checkbox"/> Corrosive	<input type="text"/>
<input type="checkbox"/> Oxidizer	<input type="text"/>
<input type="checkbox"/> Contact Hazard	<input type="text"/>
Does the product have an Aerosol class? If yes, identify NFPA Storage Level:	
NFPA Storage Level:	<input type="text"/>
Is the product a NIOSH hazardous drug?	
If yes, indicate which:	<input type="text"/>

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

REMS or REGISTRY RESTRICTIONS	
<b>Is there a REMS on this product?</b>	
If Yes, is it managed with a pharmacy registry?	<input type="text"/>
Website URL:	<input type="text"/>
<b>Med Guide Required</b>	
Limited Distribution Requirement	<input type="text"/>
Comments / Details: (For example, iPledge program?)	<input type="text"/>
<b>REMS:</b>	
REMS Program Manager Name:	<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"/>
NCPDP#:	<input type="text"/>
NPI #:	<input type="text"/>
Comments	<input type="text"/>
<b>Registry:</b>	
Registry Program Contact Name:	<input type="text"/>
Phone:	<input type="text"/>
Comments	<input type="text"/>

RETURN INSTRUCTIONS	
Contact tel. # if product received damaged:	<input type="text"/>
Is product returnable for credit:	<input type="text"/>
URL/Link to returns policy:	<input type="text"/>
Special regulations or returns requirements for this product in certain states?	
If so, which states? Other requirements? Comments:	<input type="text"/>



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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"/></p> <p>c. Fax <input type="checkbox"/></p> <p>d. Phone only <input type="checkbox"/></p> <p>e. Supplier Web Site only <input type="checkbox"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/></p> <p>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Phone No.: <input type="text"/></p> <p>Site Address: <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>
<p><b>Expedited Freight Charges or Other Designated Drop Ship Fees:</b></p> <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 type="text"/></p>	<p><b>Overnight and Priority Overnight PO Processing</b></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: <input type="text"/></p> <p>Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>
<p><b>Class of Trade Restriction:</b></p> <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 type="text"/></p>	
<p><b>Other Data Information Required to Process PO:</b></p> <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><b>Return Instructions</b></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 type="text"/></p>
<p><b>Miscellaneous Notes:</b></p> <p><input type="text"/></p>	<p><b>ADDITIONAL INFORMATION</b></p> <p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>