



# Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:  New Item

Final Version

Date:

PRODUCT INFORMATION	
Company Name:	Camber Pharmaceuticals
Application:	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	212378
DUNS:	826774775
Proprietary Name (if Applicable) and Established Name:	Baclofen Tablets, USP 20mg 1000 Ct.
Selling Unit NDC:	31722-999-10
Individual Unit NDC:	
UPC:	331722999016
UDI	
CVX Code:	
MXV Code:	
Description:	White to off-white, round, flat tablet with bevel edge, debossed "I 115" on one side and scored on the other side
Active Ingredient(s):	Baclofen, USP
URL for Additional Product Information:	www.camberpharma.com
Address:	1031 Centennial Avenue
City:	Piscataway
Key Contact:	Customer Service
Phone Number:	732-529-0430
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° F)
Other Temperature Range Requirement (write in)	
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:	Soma Raju
Number:	732-529-0423
Group E-mail:	somaraju@heterousa.com
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:	
Initial shelf life at launch (if different):	24 Months
	12/ 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... Neither	
If Unit Dose, is item bar coded to unit dose for hospital scanning?	No
If Unit Dose NDC, indicate NDC here:	
Country of Origin	USA
Is this product covered under the Trade Agreements Act (TAA)?	

PRODUCT DESCRIPTION INFORMATION	
Size:	1000
Strength:	20 mg
Dosage Form:	Solid Oral Tablets
Product Shape:	Round
Product Color:	White to off white
Product Imprint:	I 115

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 bottle of 1000 tablets
<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	Minimum order quantity? 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	12 Each
<input type="checkbox"/> Vial Powder Sgl	Inner/Carton/Pack
<input type="checkbox"/> Vial Powder Multi	Case
<input type="checkbox"/> Other: Write In	

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	LIORESAL
<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:
(Write-in, e.g. 1 Vial)	<input 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?	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:	0331722000000
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		
Box/Carton/Bundle/Inner Pack:						
Case:	13.05	14	7.5	11		12
Pallet:						55
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION						
Serialized?	Level	Saleable Unit		Quantity	GTIN-14	If not, when?
		Item	Unit			
<input checked="" type="checkbox"/>	Box/Carton/Bundle/Inner Pack	<input checked="" type="checkbox"/>	2D	1	00331722999106	
<input type="checkbox"/>	Case	<input checked="" type="checkbox"/>	2D	12	10331722999103	
<input type="checkbox"/>	Pallet		2D			
<input type="checkbox"/>			2D			
<input type="checkbox"/>			2D			
<input type="checkbox"/>			2D			
<input type="checkbox"/>			2D			
<input type="checkbox"/>			2D			
<input type="checkbox"/>			2D			

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$111.24	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.)  Yes

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)  No

a. UN/Identification Number

b. Proper Shipping Name

c. DOT Hazard Class

d. Packing Group

e. Inhalation Hazard?  No

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

Passenger  
 Cargo  
 Passenger & Cargo

Is this a reportable quantity?  No  
 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  No

Restricted to retail pharmacy only:  No

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

Restricted from US territories? (explain in comments)  No

Comments:

**SDS Hazard Classification**

Organic  Corrosive  
 Inorganic  Oxidizer  
 Steroid/Androgen  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:**  No  
 Registry Program Contact Name:  Phone:

Comments

**RETURN INSTRUCTIONS**

Contact tel. # if product received damaged:

Is product returnable for credit:  Yes  
 URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states?  No

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> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">a. EDI</td> <td style="width: 15%;"><input type="text"/></td> <td style="width: 15%;"></td> <td style="width: 15%;"></td> <td style="width: 15%;"></td> <td style="width: 20%;"></td> </tr> <tr> <td>b. Autofax</td> <td><input type="text"/></td> <td>Fax Number:</td> <td><input type="text"/></td> <td></td> <td></td> </tr> <tr> <td>c. Fax</td> <td><input type="text"/></td> <td>Fax Number:</td> <td><input type="text"/></td> <td></td> <td></td> </tr> <tr> <td>d. Phone only</td> <td><input type="text"/></td> <td>Phone No.:</td> <td><input type="text"/></td> <td></td> <td></td> </tr> <tr> <td>e. Supplier Web Site only</td> <td><input type="text"/></td> <td>Site Address:</td> <td><input type="text"/></td> <td></td> <td></td> </tr> </table> <p>Minimum Order Quantity: <input style="width: 80%;" type="text"/></p> <p>Supplier's Customer Service Number: <input style="width: 95%;" type="text"/></p> <p>Contracted 3PL company / contact #:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Name:</td> <td><input style="width: 80%;" type="text"/></td> </tr> <tr> <td>Phone:</td> <td><input style="width: 80%;" type="text"/></td> </tr> </table>	a. EDI	<input type="text"/>					b. Autofax	<input type="text"/>	Fax Number:	<input type="text"/>			c. Fax	<input type="text"/>	Fax Number:	<input type="text"/>			d. Phone only	<input type="text"/>	Phone No.:	<input type="text"/>			e. Supplier Web Site only	<input type="text"/>	Site Address:	<input type="text"/>			Name:	<input style="width: 80%;" type="text"/>	Phone:	<input style="width: 80%;" type="text"/>	<p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <input style="width: 150px;" type="text"/> Eastern</p> <hr/> <p>Shipping lead time of PO: <input style="width: 50px;" type="text"/> Hours <input style="width: 50px;" type="text"/> Days</p> <p>Ships same day for next day receipt: <input style="width: 50px;" type="text"/></p> <p>Ships for second day receipt: <input style="width: 50px;" type="text"/></p> <p>Ships regular ground for 3-10 days receipt: <input style="width: 50px;" type="text"/></p>
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d. Phone only	<input type="text"/>	Phone No.:	<input type="text"/>																																
e. Supplier Web Site only	<input type="text"/>	Site Address:	<input type="text"/>																																
Name:	<input style="width: 80%;" type="text"/>																																		
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Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing																																		
<p>Expedited freight fees billed with each order: <input style="width: 80px;" type="text"/></p> <p>Drop Ship service fee billed with each order: <input style="width: 80px;" type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input style="width: 80px;" type="text"/></p> <p>Comments: <input style="width: 100%; height: 80px;" type="text"/></p>	<p><b>Overnight receipt available:</b> <input style="width: 50px;" type="text"/></p> <p>PO Receipt cut off time: <input style="width: 150px;" type="text"/> Eastern</p> <p>Days of week overnight is available:</p> <table style="width: 100%; border-collapse: collapse;"> <tr><td><input type="checkbox"/></td><td>Monday</td></tr> <tr><td><input type="checkbox"/></td><td>Tuesday</td></tr> <tr><td><input type="checkbox"/></td><td>Wednesday</td></tr> <tr><td><input type="checkbox"/></td><td>Thursday</td></tr> <tr><td><input type="checkbox"/></td><td>Friday</td></tr> </table> <p><b>Priority Overnight receipt available:</b> <input style="width: 50px;" type="text"/></p> <p>PO Receipt Cut off time: <input style="width: 150px;" type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input style="width: 50px;" type="text"/></p> <p>PO Receipt Cut off time: <input style="width: 150px;" type="text"/></p> <p>Order receipt method:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;">Phone:</td> <td style="width: 15%;"><input style="width: 80px;" type="text"/></td> <td style="width: 15%;">Phone #:</td> <td style="width: 15%;"><input style="width: 80px;" type="text"/></td> </tr> <tr> <td>Fax:</td> <td><input style="width: 80px;" type="text"/></td> <td>Fax #:</td> <td><input style="width: 80px;" type="text"/></td> </tr> <tr> <td>EDI:</td> <td><input style="width: 80px;" type="text"/></td> <td></td> <td></td> </tr> </table> <p>Overnight Fees apply: <input style="width: 50px;" type="text"/></p> <p>Other fees apply: <input style="width: 50px;" type="text"/></p>	<input type="checkbox"/>	Monday	<input type="checkbox"/>	Tuesday	<input type="checkbox"/>	Wednesday	<input type="checkbox"/>	Thursday	<input type="checkbox"/>	Friday	Phone:	<input style="width: 80px;" type="text"/>	Phone #:	<input style="width: 80px;" type="text"/>	Fax:	<input style="width: 80px;" type="text"/>	Fax #:	<input style="width: 80px;" type="text"/>	EDI:	<input style="width: 80px;" type="text"/>														
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EDI:	<input style="width: 80px;" type="text"/>																																		
Class of Trade Restriction:	Return Instructions																																		
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input style="width: 30px;" type="text"/> No</p> <p>Restricted to retail pharmacy only: <input style="width: 30px;" type="text"/> No</p> <p>Restricted to hospital, clinics, and physician offices only: <input style="width: 30px;" type="text"/> No</p> <p>Restricted from US territories? (explain in comments) <input style="width: 30px;" type="text"/> No</p> <p>Comments: <input style="width: 100%; height: 40px;" type="text"/></p>	<p>Contact # if product is received damaged: <input style="width: 150px;" type="text"/></p> <p>Is product returnable for credit: <input style="width: 150px;" type="text"/></p> <p>URL/Link to returns policy: <input style="width: 150px;" type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input style="width: 50px;" type="text"/></p> <p>If so, which states? Other requirements? Comments?</p> <p><input style="width: 100%; height: 40px;" type="text"/></p>																																		
Other Data Information Required to Process PO:	ADDITIONAL INFORMATION																																		
<p>Patient Procedure Date: <input style="width: 150px;" type="text"/></p> <p>Physician Name: <input style="width: 300px;" type="text"/></p> <p>Physician/Clinic Phone #: <input style="width: 300px;" type="text"/></p> <p>Physician State License #: <input style="width: 300px;" type="text"/></p> <p>Physician/Clinic DEA #: <input style="width: 300px;" type="text"/></p> <p>Physician/Clinic Specialty: <input style="width: 300px;" type="text"/></p>	<p>Is product order for scheduled patient procedure? <input style="width: 50px;" type="text"/></p> <p>Is product order for restocking purposes? <input style="width: 50px;" type="text"/></p>																																		
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