Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: New Item | [ ] Final Version | **Date:** 2/27/2018

PRODUCT INFORMATION

Company Name:	ZYDUS PHARMACEUTICALS (USA) INC.	**Application:**	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	202900		
DUNS:	156861945		
Proprietary Name (If Applicable) and Established Name:	BUMETANIDE TABLETS, USP 0.5MG 100 COUNT		
Selling Unit NDC:	68382-525-01	**Individual Unit NDC:**	**UPC:** 368382525017
UDI		**CVX Code:**	**MVX Code:**
Description:	Light green, round, biconvex, uncoated tablet debossed with '525' on one side separating '5' & '25' with breakline and plain on the other side.		
Active Ingredient(s):	BUMEX		
URL for Additional Product Information:			

Address:	73 ROUTE 31 NORTH	**Address 2:**	
City:	PENNINGTON	**State:** NJ	**Zip:** 08534
Key Contact:		**Email:**	
Phone Number:	(609) 730 1900	**Fax:**	(609) 730 1998
Product Therapeutic Classification:			

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	
Is this product covered under the Trade Agreements Act (TAA)?	

PRODUCT DESCRIPTION INFORMATION

Size:	100 COUNT
Strength:	0.5MG
Dosage Form:	TABLETS
Product Shape:	ROUND
Product Color:	LIGHT GREEN
Product Imprint:	"525" - 5 & 25

FOR GENERIC DRUG PRODUCTS

[ ] Authorized Generic — *If Authorized Generic, other section fields are not applicable

I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	BUMEX

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?	Yes	**GLN:**	036382000002
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		
Has FDA granted waiver/exception/exemption for product?	No	**If yes, attach documentation from FDA.**	

GTIN PRODUCT INFORMATION

Serialized? No
If not, when? 7/1/2018
Items aggregated? Yes

Level		Saleable Unit		2D		Linear	Quantity	GTIN-14
X	Item	X	X	2D		Linear	1	00368382525017
	Box/Carton/Bundle/Inner Pack			2D		Linear		
X	Case		X	2D		Linear	24	40368382525015
X	Pallet		X	2D		Linear		80368382525013
				2D		Linear		
				2D		Linear		
				2D		Linear		
				2D		Linear		

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)	
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:	
Number:	
Group E-mail:	

c. Special regulations for product in any states?	No	
Special returns requirements for this product?		
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):		**Months**

ORDER INFORMATION

Unit of Sale

X	Bottle
	Box/Carton
	Ampule
	Glass
	Tube
	Vial Liquid Sgl
	Vial Liquid Multi
	Vial Powder Sql
	Vial Powder Multi
	Other: Write In

What is the NDC selling unit?
1 BOTTLE OF 100 TABLETS
(Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity? Yes

If Yes, how many of which package type?

	Each
	Inner/Carton/Pack
X	Case

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?
(Write-in, e.g. 1 Vial)

Rx billing unit to pharmacy:

X	Each
	Gram
	Milliliter

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.) Depth	Height	Width	Volume (Cube)	# Pieces:
Item:	0.08	1.61	2.98	1.61	7.724458	1
Box/Carton/Bundle/ Inner Pack:					0	
Case:	3.1	9.72	6.49	3.81	240.345468	24
Pallet:	632.42	48	40	48	92160	4752
UPC:	**Case:**					
	Carton:					

COST INFORMATION

Regular Cost	
Invoice Cost (WAC) ($)	$82.26
Federal Excise Tax Per Unit of Sale	
As of date:	7/3/2018

WHOLESALER USE ONLY:

Vendor #:	
Whsl. Code #:	
Fineline Code:	

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: