



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: Post Launch Change

Final Version

Date:

PRODUCT INFORMATION	
Company Name:	ZYDUS PHARMACEUTICALS (USA) INC.
Application:	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	206134
DUNS:	156861945
Proprietary Name (If Applicable) and Established Name:	BUDESONIDE CAPSULES, 3mg
Selling Unit NDC:	68382-720-01
Individual Unit NDC:	
UPC:	368382720016
UDI	
CVX Code:	
MVX Code:	
Description:	white to off-white, free flowing pellets, filled in size '1' hard gelatin capsules having opaque light-orange colored cap printed with "720" in black ink and opaque white body.
Active Ingredient(s):	BUDESONIDE
URL for Additional Product Information:	
Address:	73 ROUTE 31 NORTH
City:	PENNINGTON
State:	NJ
Address 2:	
Zip:	08534
Key Contact:	
Phone Number:	(609) 730 1900
Fax:	(609) 730 1998
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?	<input type="checkbox"/> No
Is this product to be shipped to customers on dry ice?	<input type="checkbox"/> No
b. Contact for temperature excursion questions:	
Name:	
Number:	
Group E-mail:	
c. Special regulations for product in any states?	<input type="checkbox"/> No
Special returns requirements for this product?	
d. Store product (unit of sale) upright?	<input type="checkbox"/> No
Protect product (unit of sale) from light?	<input type="checkbox"/> No
e. Shelf life:	
Initial shelf life at launch (if different):	<input type="text" value="24"/> Months

ADDITIONAL PRODUCT INFORMATION	
Is the Product... a legend device?	<input type="checkbox"/> No
reverse numbered?	<input type="checkbox"/> No
co-licensed?	<input type="checkbox"/> No
Is the Product... Direct-Ship Only?	<input type="checkbox"/>
Is the Product... Neither?	<input type="checkbox"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/>
If Unit Dose NDC, indicate NDC here:	<input type="text"/>
Country of Origin	<input type="text"/>
Is this product covered under the Trade Agreements Act (TAA)?	<input type="checkbox"/>

PRODUCT DESCRIPTION INFORMATION	
Size:	100 COUNT
Strength:	3MG
Dosage Form:	CAPSULES
Product Shape:	CAPSULE
Product Color:	OPAQUE LIGHT-ORANGE/OPAQUE WHITE
Product Imprint:	720

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 BOTTLE OF 100 CAPSULES
<input 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? <input type="checkbox"/> Yes
	If Yes, how many of which package type?
	<input type="checkbox"/> Each
	<input type="checkbox"/> Inner/Carton/Pack
	<input checked="" type="checkbox"/> Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	ENTOCORT
<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:
<input type="text" value="(Write-in, e.g. 1 Vial)"/>	<input checked="" 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?	<input type="checkbox"/> Yes
Is product exempt from DSCSA?	<input type="checkbox"/> No
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	<input type="checkbox"/> No
Is product sold by manufacturer's exclusive distributor?	<input type="checkbox"/> No
Has FDA granted waiver/exception/exemption for product?	<input type="checkbox"/> No
GLN:	036382000002
If Yes, was original product purchased direct from mfr?	<input type="checkbox"/>
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Depth	Height	Width	Volume (Cube)	# Pieces:
Item:	0.17	2.23	3.74	2.23	18.598646	1
Box/Carton/Bundle/Inner Pack:					0	
Case:	6.23	13.27	8.86	5.12	601.969664	24
Pallet:	585	48	40	48	92160	2184
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION						
Serialized?	Level	Saleable Unit	Quantity	GTIN-14		
<input type="checkbox"/> No	<input checked="" type="checkbox"/> Item	<input checked="" type="checkbox"/>	1	00368382720016		
If not, when? <input type="text" value="3/1/2018"/>	<input type="checkbox"/> Box/Carton/Bundle/Inner Pack	<input type="checkbox"/>				
Items aggregated? <input type="checkbox"/> Yes	<input checked="" type="checkbox"/> Case	<input type="checkbox"/>	24	40368382720014		
	<input checked="" type="checkbox"/> Pallet	<input type="checkbox"/>		80368382720012		

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$445.00	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:	5/1/2018		