

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014 Introduction Type: New Item							F	Final Version		Date:	4/28/	2015		
		F	RODUCT INFORMATI	ON					SPECIAL HA	NDLING AND S	TORAGE REQU	IIREMENTS*		
Company Name: Zydus Pharmaceuticals USA Inc. Application: ANDA						a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/ANDA/BLA, Med Device:			90739					I. Freezer – between -25 and -10 C (-13° – 14° F)						
			layed Release Capsules, 60mg 30s						II. Cold – betwee	en 2 and 8 C (36	° – 46° F)			
NDC:	68382-387-06			UPC:	368382387066				III. Cool – betwee					
CVX Code: MVX Co							IV. Controlled Room – between 20 and 25 C (68° – 77° F)							
Description: white to off-white free flowing pellets filled in size '1' hard gelatin capsules with blue-colored cap p					e-colored cap printed	with "243" in gold	den ink				n 15 and 30 C (5			
and white-colored body printed with "60 mg" in golden ink Active ingredients: Duloxetine Hydrochloride								V. Avoid Excessi VI. Other Tempe		, ,				
, ,								(write in)						
URL for Additional Produ		www.zydususa						VII. No Requirement						
Address:	73 Route 31 North		Address 2:		Zip: 08534			b. Contact for temperature excursion questions:						
City: Key Contact:	Pennington		State: NJ Email:		Zip: 08534			Name: Number:						
Phone Number:			Fax: (609) 730 199		91					d to customers o	on ice?	No		
THOUGHT HAMILE	(000) 100 1000	FOR	GENERIC DRUG PRODUCTS					Is this product to be shipped to customers on ice? Is this product to be shipped to customers on dry ice?				No		
L Oranga Back Batings	AB	1011	_					·			•	140		
I. Orange Book Rating: III. Generic Equivalent for		Duloxetine Dela	II. Brand Name: Cymbalta layed Release Capsules, 60mg 30s					c. Special regulations for product in certain states?						
III. Generio Equivalenti io			AIN SECURITY ACT (DSCSA) INFORMATION						•			No No		
								Special retu	urns requirement	is for this produc	μŗ	INO		
Does supplier meet DSCSA definition of manufacturer?			Yes DUNS: 156861945						1 (% . ()			Yes		
Is product exempt from DSCSA? No			_											
If yes, select exemptio Other exemption - Writ								Protect pr	oduct (unit of s	sale) from light	?	No		
·		No	If Yes, was original product purchased direct from mfr?					e. Shelf life:	24	Months				
Is product repackaged? No Is product sold by manufacturer's exclusive distributor?														
Is product sold by manuf	facturer's exclusive o		_	ginai product purc	nased direct from m	TT ?		e. Shell lile:	24 Initial shelf li		different):		Months	
Is product sold by manuf Are any waivers granted		distributor?	No No	<u> </u>	documentation from	_		e. Shell lile:		ife at launch (if	different):		Months	
		distributor? de?	No	If yes, attach		_		e. Shell life:	Initial shelf li		,		Months	
Are any waivers granted	for product ID/barco	distributor? de?	No No	If yes, attach	documentation from	_			Initial shelf li	ife at launch (if	ORMATION	Volume		
		distributor? de?	No No	If yes, attach	documentation from	_		Weight Lbs.	Initial shelf li	ife at launch (if	ORMATION	Volume (Cube)	Months # Pieces:	
Are any waivers granted Is the Product	for product ID/barco	distributor? ode? ADDITIONAL I	No No PRODUCT INFORMAT	If yes, attach	documentation from	_	ltam:	Weight Lbs.	Initial shelf li	PACKING INF DEPACKING INF DEPACKING INF DEPACKING INF DEPACKING INFO	ORMATION ismts.) Width:	(Cube)	# Pieces:	
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