

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014 Introduction Type: New Item						Fir	nal Version		Date:	8/25/	2014	
PRODUCT INFORMATION						:	SPECIAL HAN	NDLING AND S	TORAGE REQU	JIREMENTS*		
Company Name:	als USA Inc.	Application: ANDA			DA	a. Temperature – Indicate the USP temperature range for this product.						
Application Number for NDA/ANDA/BLA, Med Device:			090-175	I. Freezer – between -25 and -10 C (-13° – 14° F)								
Rx Product/Proprietary Name: Donepezil HCl			Orally Disintegrating Table		Cold - betwee	n 2 and 8 C (36	° – 46° F)	,				
NDC: 68382-346-06			Crany Dionicograting Table	UPC:	368382346063	II. Cold – between 2 and 8 C (36° – 46° F) III. Cool – between 8 and 15 C (46° – 59° F)						
CVX Code:	00002 0 10 00			MVX Code:	00002010000				,	20 and 25 C (68	° – 77° F)	
Description:	Mhito to off white re	und shapad biggs	onvex, uncoated tablets debossed with "ZF14" on one side and plain on the other side.				allows for excursions between 15 and 30 C (59° – 86° F)					
Description.	vville to on-write, ic	unu-snapeu, bicoi	ivex, uncoated tablets debossed with 2F14 on one side and plain on the other side.				V. Avoid Excessive Heat – above 40 C (>104° F)					
Active ingredients:		Donepezil		VI. Other Temperature Range Requirement								
		·		(write in)								
URL for Additional Product Information: www.zydususa			com	VII. No Requirement								
Address:	dress: 73 Route 31 North			Address 2:		b. Contact for temperature excursion que			xcursion ques	tions:		
City:	Pennington		State: NJ		Zip: 08534		Name:					
Key Contact:	()			Email:			Number:					
Phone Number:	(609) 730 1900		(609) 730 1991						to customers of		No	
		FOR	GENERIC DRUG PRODUCTS				Is this produc	t to be shipped	d to customers of	on dry ice?	No	
I. Orange Book Rating:	AB		II. Brand Name:	Aricept ODT								
III. Generic Equivalent for	r Brand:	Donepezil HCL	Orally Disintegrating Tablets, 5 mg, 30 ct				c. Special regu	lations for pro	oduct in certaiı	n states?	No	
	DR	UG SUPPLY CHA	AIN SECURITY ACT (DSCSA) INFORMATION				Special return	ns requirement	s for this produc	ct?	No	
Does supplier meet DSC	SA definition of man	ufacturer?	Yes DUNS : 156861945									
Does supplier meet DSCSA definition of manufacturer? Is product exempt from DSCSA? No			100001940				d. Store produ	ict (unit of sal	e) upright?		Yes	
							-	•	,	2		
If yes, select exemptio Other exemption - Writ							Protect prot	auct (unit or s	ale) from light	ſ	No	
·	ie iii.	NI.	If Yes, was original product purchased direct from mfr?						1			
Is product repackaged? No Is product sold by manufacturer's exclusive distributor?												
	facturarie avelueiva		_	al product purci	nased direct from mfr?		e. Shelf life:	24 Initial shalf li	Months	different):		Months
Is product sold by manuf		distributor?	If Yes, was origin No No						Months fe at launch (if	different):		Months
		listributor? de?	No No	If yes, attach	documentation from FDA			Initial shelf li	fe at launch (if	,		Months
Is product sold by manuf Are any waivers granted	for product ID/barco	listributor? de?	No	If yes, attach	documentation from FDA			Initial shelf li	fe at launch (if	ORMATION	Valuma	Months
Is product sold by manuf Are any waivers granted Is the Product		de? ADDITIONAL F	No No PRODUCT INFORMATION	If yes, attach	documentation from FDA			Initial shelf li ITEM AND Dim	PACKING INF	ORMATION nsmts.)	Volume (Cube)	Months # Pieces:
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