

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014 Introduction Type: New Item								Fir	nal Version		Date:	8/25/	/2014
		Р	RODUCT INFORMATION						SPECIAL HAN	NDLING AND S	TORAGE REQL	JIREMENTS*	
Company Name: Zydus Pharmaceuticals USA Inc. Application: ANDA							a. Temperature – Indicate the USP temperature range for this product.						
Application Number for NI		77-290					I. Freezer – between -25 and -10 C (-13° – 14° F)						
Rx Product/Proprietary Name		drochloride Tablets, USP 10 mg, 100 ct								•	,		
NDC: 68	Chyocodone riye	UPC: 368382794017					II. Cold – between 2 and 8 C (36° – 46° F) III. Cool – between 8 and 15 C (46° – 59° F)						
CVX Code: MVX Code:							x IV. Controlled Room – between 20 and 25 C (68° – 77° F)						
Description: Pink round, flat face, bevel edge tablets, debossed "NP" (closed P) with a partial bisect on one side and "12" on the other.							r				n 15 and 30 C (5	,	
i ilik toutiu, ilat lace, bevel euge tablets, debossed TVF (closed F) with a partial bisect on the side and TZ on the other.							١.	□ v			e 40 C (>104° F)	•	
Active ingredients: Oxycodone										rature Range R	, ,		
									(write in)		- 1]
URL for Additional Product I	www.zydususa.	.com					VII. No Requirement						
Address: 73 Route 31 North			Address 2:					b. Contact for	temperature e	xcursion ques	tions:		
City:	Pennington		State: NJ		Zip: 08534			Name:					
Key Contact:			Email:					Number:					
Phone Number: (609) 730 1900			Fax: (609) 730 1991					Is this produc	ct to be shipped	d to customers of	on ice?	No	
	FOR (GENERIC DRUG PRODUCTS					Is this produc	ct to be shipped	d to customers of	on dry ice?	No		
I. Orange Book Rating: AE	В		II. Brand Name:	Roxicodone									•
III. Generic Equivalent for Br	Oxycodone Hyd	rdrochloride Tablets, USP 10 mg, 100 ct					c. Special regulations for product in certain states?				No		
-	G SUPPLY CHA	AIN SECURITY ACT (DSCSA) INFORMATION					Special return	ns requirement	s for this produc	rt?	No	•	
Dana sumulian maad DCCCA							opoola. Fotal.		o ioi uno produc			•	
Does supplier meet DSCSA definition of manufacturer?			Yes DUNS: 156861945					d Ctanad.		a)		V	
Is product exempt from DSCSA? No			_					d. Store produ	•	,		Yes	-
If yes, select exemption:								Protect pro	duct (unit of s	ale) from light	?	No	-
Other exemption - Write in	n:								-				
Is product repackaged?		No	If Yes, was original product purchased direct from mfr?					e. Shelf life:	24	Months			1
Is product sold by manufacturer's exclusive distributor?										difforont).			
									initiai sneif ii	fe at launch (if	unierent).		Months
Are any waivers granted for	product ID/barcod	e?	No		documentation from FD)A				,	,		Months
Are any waivers granted for	product ID/barcod	e?		N)A				PACKING INF	,		Months
Is the Product Dir	product ID/barcod	e? Additional F	No PRODUCT INFORMATION	ORDER INFOR	RMATION	OA		Weight Lbs.	ITEM AND	PACKING INF	ORMATION	Volume	
Is the Product Di		e? ADDITIONAL F	No PRODUCT INFORMATION Unit of Sale	ORDER INFOR		DA		Weight Lbs.	ITEM AND	PACKING INF	ORMATION	Volume (Cube)	# Pieces:
Is the Product Di Legend Device? State Control?		ADDITIONAL F No Yes	No PRODUCT INFORMATION Unit of Sale x Bottle	ORDER INFOR	RMATION	DA .	Item:	Weight Lbs.	ITEM AND	PACKING INF	ORMATION		
Is the Product Di Legend Device? State Control? ARCOS reportable?		No Yes Yes	No PRODUCT INFORMATION Unit of Sale X Bottle Box/Carton	ORDER INFOR What is the N	RMATION NDC selling unit?□	DA .		_	ITEM AND	PACKING INF ensions (US m Height	ORMATION nsmts.) Width:	(Cube) 5.7171	
Is the Product Di Legend Device? State Control? ARCOS reportable? Co-Licensed?		No Yes Yes No	No PRODUCT INFORMATION Unit of Sale x Bottle Box/Carton Ampule	ORDER INFOR What is the N	RMATION	DA .	Box/	_	ITEM AND	PACKING INF ensions (US m Height	ORMATION nsmts.) Width:	(Cube)	
Is the Product Di Legend Device? State Control? ARCOS reportable?		No Yes Yes	No PRODUCT INFORMATION Unit of Sale X Bottle Box/Carton	ORDER INFOR What is the N	RMATION IDC selling unit? . 1 Box of 10 Vials)	Yes	Box/ Carton:	22.95 G	Depth	PACKING INF nensions (US m Height 3.23	ORMATION asmts.) Width:	(Cube) 5.7171 0	# Pieces:
Is the Product Di Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance?		No Yes Yes No	No PRODUCT INFORMATION Unit of Sale X Bottle Box/Carton Ampule Glass	ORDER INFOR What is the N Each (Write-in, e.g.	RMATION IDC selling unit? . 1 Box of 10 Vials)		Box/	_	ITEM AND	PACKING INF ensions (US m Height	ORMATION nsmts.) Width:	(Cube) 5.7171	
Is the Product Di Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.?	irect Ship Item	No Yes Yes No Yes Yes	No PRODUCT INFORMATION Unit of Sale X Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi	ORDER INFOR What is the N Each (Write-in, e.g.	RMATION IDC selling unit? . 1 Box of 10 Vials)	Yes	Box/ Carton: Case:	22.95 G	Dim Depth	PACKING INF nensions (US m Height 3.23	ORMATION DESMITS.) Width: 1.77 7.5	(Cube) 5.7171 0 199.5	# Pieces:
Is the Product Discription of the Product Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.?	irect Ship Item	No Yes Yes No	No Unit of Sale X Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql	ORDER INFOR What is the N Each (Write-in, e.g.	RMATION NDC selling unit? . 1 Box of 10 Vials) der quantity? nany of which package ty Each	Yes	Box/ Carton:	22.95 G 0.67LBS	Depth	PACKING INF nensions (US m Height 3.23	ORMATION asmts.) Width:	(Cube) 5.7171 0	# Pieces:
Is the Product Di Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcotic) Controlled Substance Code: Hazardous Material/Cytotoxi	irect Ship Item	No Yes Yes No Yes Yes	No PRODUCT INFORMATION Unit of Sale x Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi Vial Powder Sql Vial Power Multi	ORDER INFOR What is the N Each (Write-in, e.g.	RMATION NDC selling unit? . 1 Box of 10 Vials) der quantity? nany of which package ty Each Inner/Carton/Pack	Yes	Box/ Carton: Case:	22.95 G 0.67LBS Case:	Dim Depth	PACKING INF nensions (US m Height 3.23	ORMATION DESMITS.) Width: 1.77 7.5	(Cube) 5.7171 0 199.5	# Pieces:
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