## NDA [22-173] Risk Evaluation and Mitigation Strategy

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POST INJECTION DELI	RIUM/SEDATION SYND	ROME (PDSS) FORM	PDSS Page 1 of 3		
<b>ZYPTEXT</b> Relprevo (olanzapine) For Extended Release Injectable Suspension	Submit this informatio suspected PDSS ever	n within <b>24 hours</b> of becoming ant.	aware of a		
Patient No.: (PIN) Patient Name: First Name Date of Birth: day year	MI Last Name				
Does the patient have a diagnosis of schizophi	enia? ☐ Yes ☐ No				
PATIENT/INJECTION INFORMATION					
Date of Injection:	year Co	nvenience Kit Package			
Time of ZYPREXA RELPREVV Injection 24	Lot	#			
	inutes  inutes (1 ½ hours)	121 - 150 minutes (2 ½ hours) 151 - 180 minutes (3 hours) If greater than 3 hours please specify: Hours			
Dose of Injection: 150 mg 210 mg	☐ 300 mg ☐ 405 mg	Other dose mg			
Was the injection given in gluteal muscle?					
Height (inches) Weight: (lbs.)					
PDSS SIGNS AND SYMPTOMS					
Please mark the signs and s	ymptoms that the patient experienced (	check all that apply)			
☐ Aggressiveness       ☐ Coma         ☐ Agitation       ☐ Confusion         ☐ Anxiety       ☐ Convulsion/Seizure         ☐ Aspiration       ☐ Delirium         ☐ Ataxia       ☐ Disorientation         ☐ Cardiac arrhythmias       ☐ Dizziness         ☐ Cardiopulmonary arrest       ☐ Dysarthria	Hypertension Hypotension Other cognitive impairment Possible neuroleptic malignant syndrome Reduced level of consciousness Respiratory depression Sedation	Tachycardia Various extrapyramidal symptoms Weakness Other Other Other			
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POST INJECTION	DELIRIUM/SEDAT	TION SYNDROM	ME (PDSS) FORM	PDSS Page 2 of 3
Patient No.:				
Patient Name: First Name	MI	Last Name		
PDSS start date:	- year			
PDSS resolution date:		OR Ongoing		
If resolved, duration of PDSS:	ay year	☐ Minutes ☐ Hour	rs Days	
Are these PDSS symptoms related to	ZYPREXA RELPREVV?			
Yes				
No - Please Explain				
Patient Outcome: (choose one)	Recovered Unknown	☐ Fatal ☐ Recovering	□ Not Recovered □ Recovered with sequelae	
Once a PDSS event was suspected, Yes No			capable of resuscitation?	
Did the patient visit the emergency ro				
Was the patient admitted to the hospi	tal as a result of the PDSS	S? ∐Yes ∐No		
Were olanzapine concentrations colle	cted? Yes No			
Did the patient receive any MEDICAT	IONS AS TREATMENT fo	or the PDSS event?		
Yes - Please record below No				
Treatment Medication Name	Dose	D	uration of Use (in Days)	
1				

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POST INJECTION DELIRIUM/SEDATION SYNDROME (PDSS) FORM			
Patient No.: (PIN) Patient Name:		M. Look Norma	
First Name		MI Last Name	
Did the patient receive any <b>NON-P</b> IDIAGNOSTIC TESTS associated v		EATMENTS or es - Please record below □ No	
Assisted ventilation Brain CT ECG	IV fluids	MRI  Dbservation/symptomatic management  Vital sign moni	toring
Please fax test results to 1-877-7	72-9391.		
STORY PRIOR TO PDSS EVENT			
Does the patient have any relevant Yes - Please specify: No			
Yes - Please specify:		rior to the injection? $\Box$ Yes - Please record below $\Box$ No	0
Yes - Please specify:No  RIOR MEDICATIONS  Did the patient take any medication	s during the 24 hours p		0
Yes - Please specify:		rior to the injection?	0
Yes - Please specify:No  RIOR MEDICATIONS  Did the patient take any medication	s during the 24 hours p	rior to the injection?	0
Yes - Please specify:No  RIOR MEDICATIONS  Did the patient take any medication	s during the 24 hours p	rior to the injection?	0
Yes - Please specify:No  RIOR MEDICATIONS  Did the patient take any medication	s during the 24 hours p	rior to the injection?	0
Yes - Please specify:No  RIOR MEDICATIONS  Did the patient take any medication	s during the 24 hours p	rior to the injection?	0
Yes - Please specify:No  RIOR MEDICATIONS  Did the patient take any medication  Prior Medication Name	s during the 24 hours p	rior to the injection?	
Yes - Please specify:No  RIOR MEDICATIONS  Did the patient take any medication  Prior Medication Name	s during the 24 hours p  Dose  Dose  ving during the 24 hours	rior to the injection?	□No
☐ Yes - Please specify: ☐ No  RIOR MEDICATIONS  Did the patient take any medication  Prior Medication Name  Did the patient use any of the follow ☐ Alcohol ☐ Amphetamines/Methamphetami  Event reported by:	s during the 24 hours p  Dose  Dose  ving during the 24 hours	rior to the injection?	□No
Yes - Please specify: No  RIOR MEDICATIONS  Did the patient take any medication  Prior Medication Name  Did the patient use any of the follow Alcohol Amphetamines/Methamphetami  Event reported by:	Dose  Dose  Dose  Dose  Dose  Dose  Ca	rior to the injection?	□No

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