

POST-INJECTION DELIRIUM/SEDATION SYNDROME (PDSS) FORM



Submit this information within **24 hours** of becoming aware of a suspected PDSS event.

Patient No (PIN)

Patient Name: _____
First Name MI Last Name

Date of Birth: - -
month day year

Does the patient have a diagnosis of schizophrenia? Yes No

PATIENT/INJECTION INFORMATION

Date of Injection: - -
month day year

Time of ZYPREXA RELPREVV Injection: :
24-hour clock

Convenience Kit Package

Lot # _____

ONSET OF FIRST PDSS SYMPTOM AFTER INJECTION (choose only one)

- | | | |
|--|--|---|
| <input type="checkbox"/> 1 - 15 minutes | <input type="checkbox"/> 46 - 60 minutes | <input type="checkbox"/> 121 - 150 minutes (2 ½ hours) |
| <input type="checkbox"/> 16 - 30 minutes | <input type="checkbox"/> 61 - 90 minutes (1 ½ hours) | <input type="checkbox"/> 151 - 180 minutes (3 hours) |
| <input type="checkbox"/> 31 - 45 minutes | <input type="checkbox"/> 91 - 120 minutes (2 hours) | <input type="checkbox"/> 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? Yes No

Height: (inches) Weight: (lbs.)

PDSS SIGNS AND SYMPTOMS

Please mark the signs and symptoms that the patient experienced (check all that apply).

- | | | | |
|---|---|--|--|
| <input type="checkbox"/> Aggressiveness | <input type="checkbox"/> Coma | <input type="checkbox"/> Hypertension | <input type="checkbox"/> Tachycardia |
| <input type="checkbox"/> Agitation | <input type="checkbox"/> Confusion | <input type="checkbox"/> Hypotension | <input type="checkbox"/> Various extrapyramidal symptoms |
| <input type="checkbox"/> Anxiety | <input type="checkbox"/> Convulsion/Seizure | <input type="checkbox"/> Other cognitive impairment | <input type="checkbox"/> Weakness |
| <input type="checkbox"/> Aspiration | <input type="checkbox"/> Delirium | <input type="checkbox"/> Possible neuroleptic malignant syndrome | <input type="checkbox"/> Other _____ |
| <input type="checkbox"/> Ataxia | <input type="checkbox"/> Disorientation | <input type="checkbox"/> Reduced level of consciousness | <input type="checkbox"/> Other _____ |
| <input type="checkbox"/> Cardiac arrhythmias | <input type="checkbox"/> Dizziness | <input type="checkbox"/> Respiratory depression | <input type="checkbox"/> Other _____ |
| <input type="checkbox"/> Cardiopulmonary arrest | <input type="checkbox"/> Dysarthria | <input type="checkbox"/> Sedation | <input type="checkbox"/> Other _____ |

FP-00-US-0070 02/2020 ©Lilly USA, LLC 2020. All rights reserved. ZYPREXA® RELPREVV™ and the ZYPREXA RELPREVV logo are registered trademarks of Eli Lilly and Company



POST-INJECTION DELIRIUM/SEDATION SYNDROME (PDSS) FORM

Patient No.:
 (PIN)

Patient Name: _____
 First Name MI Last Name

PDSS start date: - -
 month day year

PDSS resolution date: - - OR Ongoing
 month day year

If resolved, duration of PDSS: _____ Minutes Hours Days

Are these PDSS symptoms related to ZYPREXA RELPREVV?

Yes
 No - Please Explain _____

Describe the clinical course _____

Patient Outcome: (choose one) Recovered Fatal Not Recovered
 Unknown Recovering Recovered with sequelae

Once a PDSS event was suspected, was the patient's monitoring initiated in a facility capable of resuscitation? Yes No

Did the patient visit the emergency room as a result of the PDSS? Yes No

Was the patient admitted to the hospital as a result of the PDSS? Yes No

Were olanzapine concentrations collected? Yes No

Did the patient receive any **MEDICATIONS AS TREATMENT** for the PDSS event? Yes - Please record below No

Treatment Medication Name	Dose	Duration of Use (in Days)

FP-00-US-0070 02/2020 ©Lilly USA, LLC 2020. All rights reserved.
 ZYPREXA® RELPREVV™ and the ZYPREXA RELPREVV logo are registered trademarks of Eli Lilly and Company



POST-INJECTION DELIRIUM/SEDATION SYNDROME (PDSS) FORM

Patient No.:

Patient Name: _____
 First Name MI Last Name

Did the patient receive any **NON-PHARMACEUTICAL TREATMENTS** or **DIAGNOSTIC TESTS** associated with this event? Yes - Please record below No

- | | | | |
|---|------------------------------------|---|--|
| <input type="checkbox"/> Assisted ventilation | <input type="checkbox"/> EEG | <input type="checkbox"/> MRI | <input type="checkbox"/> Urine drug screen |
| <input type="checkbox"/> Brain CT | <input type="checkbox"/> IV fluids | <input type="checkbox"/> Observation/symptomatic management | <input type="checkbox"/> Vital sign monitoring |
| <input type="checkbox"/> ECG | <input type="checkbox"/> Labs | <input type="checkbox"/> Restraints | <input type="checkbox"/> Other _____ |

Please fax test results to 1-877-772-9391.

HISTORY PRIOR TO PDSS EVENT

Does the patient have any relevant comorbidities?

- Yes - Please specify: _____
- No

PRIOR MEDICATIONS

Did the patient take any medications during the 24 hours prior to the injection? Yes - Please record below No

Prior Medication Name	Dose	Duration of Use			
		Number	Choose One		
			<input type="checkbox"/> Days	<input type="checkbox"/> Months	<input type="checkbox"/> Years
			<input type="checkbox"/> Days	<input type="checkbox"/> Months	<input type="checkbox"/> Years
			<input type="checkbox"/> Days	<input type="checkbox"/> Months	<input type="checkbox"/> Years
			<input type="checkbox"/> Days	<input type="checkbox"/> Months	<input type="checkbox"/> Years
			<input type="checkbox"/> Days	<input type="checkbox"/> Months	<input type="checkbox"/> Years

Did the patient use any of the following during the 24 hours prior to the injection? Yes - Please record below No

- | | | | |
|--|---------------------------------------|--|--|
| <input type="checkbox"/> Alcohol | <input type="checkbox"/> Barbiturates | <input type="checkbox"/> Cocaine | <input type="checkbox"/> Opiates |
| <input type="checkbox"/> Amphetamines/Methamphetamines | <input type="checkbox"/> Cannabinoid | <input type="checkbox"/> Hallucinogens | <input type="checkbox"/> Phencyclidine |

Event reported by: _____
 First MI Last

Title/Occupation: _____

If agent of the Prescriber, name of Prescriber: _____