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: mm/dd/yy

Does the patient have a diagnosis of schizophrenia? □ Yes □ No

PATIENT/INJECTION INFORMATION

Date of Injection: mm/dd/yy

Convenience Kit Package
Lot #: ________________________

Time of ZYPREXA Relprevv Injection: ________________________ 24-hour clock

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

☐ 1 - 15 minutes
☐ 16 - 30 minutes
☐ 31 - 45 minutes
☐ 46 - 60 minutes
☐ 61 - 90 minutes (1 ½ hours)
☐ 91 - 120 minutes (2 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? □ Yes □ No

Height (inches): _______

Weight (lbs.): _______

PDSS SIGNS AND SYMPTOMS

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

☐ Aggressiveness
☐ Agitation
☐ Anxiety
☐ Apnea
☐ Aspiration
☐ Axillary
☐ Cardiac arrhythmias
☐ Cardiopulmonary arrest
☐ Coma
☐ Confusion
☐ Conversion/Syncope
☐ Delirium
☐ Disorientation
☐ Dizziness
☐ Dysesthesia
☐ Hypertension
☐ Hypotension
☐ Other cognitive impairment
☐ Other neurological malignant
☐ Syndrome
☐ Possible neuroleptic malignant syndrome
☐ Reduced level of consciousness
☐ Respiratory depression
☐ Sedation
☐ Tachycardias
☐ Various extrapyramidal symptoms
☐ Weakness
☐ Other

PHONE 1 877 772 9390
FAX 1 877 772 9391
www.zprexarelprevvprogram.com

Reference ID: 3283437

Current as of 6/1/2013. This document may not be part of the latest approved REMS.
POST INJECTION DELIRIUM/SEDATION SYNDROME (PDSS) FORM

Patient No.: (PIN)

Patient Name: ____________________________  ____________________________

First Name  MI  Last Name

PDSS start date:  

months  day  year

PDSS resolution date:  

months  day  year  OR  Ongoing

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

☐ 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

<table>
<thead>
<tr>
<th>Treatment Medication Name</th>
<th>Dose</th>
<th>Duration of Use (in Days)</th>
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Patient No.: _____________________________ __________ ______________________________________________
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

☑ Assisted ventilation ☑ EEG ☑ MRI ☑ Urine drug screen
☑ Brain CT ☑ IV fluids ☑ Observation/symptomatic management ☑ Vital sign monitoring
☑ ECG ☑ Labs ☑ Restraints ☑ 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

<table>
<thead>
<tr>
<th>Prior Medication Name</th>
<th>Dose</th>
<th>Duration of Use</th>
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Did the patient use any of the following during the 24 hours prior to the injection? ☐ Yes - Please record below ☐ No

☑ Alcohol ☑ Barbiturates ☑ Cocaine ☑ Opiates
☑ Amphetamines/Methamphetamines ☑ Cannabinoid ☑ Hallucinogens ☑ Phencyclidine

Event reported by: _______________________________ __________ ________________________________________
First MI Last

Title/Occupation: ________________________________

If agent of the Prescriber, name of Prescriber: ___________________________ __________ ______________________
First MI Last