POST-INJECTION DELIRIUM/SEDATION SYNDROME (PDSS) FORM

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

**PATIENT/INJECTION INFORMATION**

<table>
<thead>
<tr>
<th>Date of Injection:</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>month</td>
<td>day</td>
<td>year</td>
<td></td>
<td></td>
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</tbody>
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<table>
<thead>
<tr>
<th>Time of ZYPREXA RELPREV V Injection:</th>
<th>:</th>
</tr>
</thead>
<tbody>
<tr>
<td>24-hour clock</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Convenience Kit Package</th>
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</thead>
<tbody>
<tr>
<td>Lot # ____________________</td>
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**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
- [ ] Aspiration
- [ ] Ataxia
- [ ] Cardiac arrhythmias
- [ ] Cardiopulmonary arrest
- [ ] Coma
- [ ] Confusion
- [ ] Convulsion/Seizure
- [ ] Delirium
- [ ] Disorientation
- [ ] Dizziness
- [ ] 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 ________________
- [ ] Other ________________

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Version 1.0 28Oct2009  CONFIDENTIAL

Reference ID: 4786995
## Patient Information

**Patient No.:**

<table>
<thead>
<tr>
<th>PIN</th>
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<tbody>
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</table>

**Patient Name:**

First Name: ___________________________  MI: ___________________________  Last Name: ___________________________

**PDSS start date:**

<table>
<thead>
<tr>
<th>month</th>
<th>day</th>
<th>year</th>
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</table>

**PDSS resolution date:**

<table>
<thead>
<tr>
<th>month</th>
<th>day</th>
<th>year</th>
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- OR
- Ongoing

If resolved, duration of PDSS: ____________________________  Minutes  Hours  Days

## PDSS Symptoms

Are these PDSS symptoms related to ZYPREXA RELPREVV?

- [ ] Yes
- [ ] No - Please Explain _______________________________________________________________________________________

Describe the clinical course _______________________________________________________________________________________

_____________________________________________________________________________________________________________

## Patient Outcome

- [ ] Recovered
- [ ] Fatal
- [ ] Not Recovered
- [ ] Recovering
- [ ] Recovered with sequelae

**Patient Outcome:** (choose one)

**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>
</tr>
</thead>
<tbody>
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Reference ID: 4786995
Patient No.: _________________________________________ 
(PIN) 

Patient Name: _________________________________________      _________      _________________________________________
First Name                                                                            MI                      Last Name

POST-INJECTION DELIRIUM/SEDATION SYNDROME (PDSS) FORM

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>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Number</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Days</td>
</tr>
</tbody>
</table>

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: _________________________________________      _________      _________________________________________

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