

Patient Monitoring Form - Outpatient Use Only

INSTRUCTIONS:

This form is intended only for use by outpatient medical offices or clinics, excluding emergency departments.

1. Complete all required fields on this form after every treatment session for all outpatients enrolled in the SPRAVATO[®] REMS.
2. Submit completed patient monitoring forms within 7 days, online at www.SPRAVATOrems.com or by fax (1-877-778-0091).

*Indicates Required Field

Patient Information (PRINT)			
First Name*:	MI:	Last Name*:	Birthdate* (MM/DD/YYYY): Sex*: <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Other
Concomitant Medication			
Is the patient currently taking any of the following medication(s) that may cause sedation or blood pressure changes?			
• Benzodiazepines*	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
• Non-benzodiazepine sedative hypnotics*	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
• Psychostimulants*	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
• Monoamine oxidase inhibitors (MAOIs)*	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Healthcare Provider Conducting Patient Monitoring (PRINT)			
First Name*:		Last Name*:	
Telephone*:		Email*:	
Healthcare Setting Information (PRINT)			
Healthcare Setting Name*:			
Healthcare Setting Address 1*:		Healthcare Setting Address 2:	
City*:	State*:	ZIP*:	
Patient Treatment Session Information (Administration and Monitoring)			
Treatment Date*	Date (MM/DD/YYYY): _____		
Dose Administered*	<input type="checkbox"/> 56 mg <input type="checkbox"/> 84 mg <input type="checkbox"/> Other: _____		
Treatment Duration*	Total time _____ minutes (from 1st device administration to completion of monitoring) Patient must be monitored for at least 2 hours		
REMS Evaluation Question*	If there was not a 2-hour minimum monitoring requirement, when would this patient have been ready to leave/no longer require monitoring? _____ minutes from start of administration		
Monitoring of Vital Signs*	Vital signs were in acceptable range prior to: • administration? <input type="checkbox"/> Yes <input type="checkbox"/> No • treatment session completion? <input type="checkbox"/> Yes <input type="checkbox"/> No		
Monitoring of Blood Pressure*	Prior to administration _____ mmHg	40 mins post-administration _____ mmHg	Prior to treatment session completion _____ mmHg
Did the patient experience Sedation and/or Dissociation			
Sedation*: <input type="checkbox"/> Yes <input type="checkbox"/> No		Dissociation*: <input type="checkbox"/> Yes <input type="checkbox"/> No	
Onset of symptoms from start of administration* <input type="checkbox"/> 1-29 mins <input type="checkbox"/> 30-59 mins <input type="checkbox"/> 60-89 mins <input type="checkbox"/> 90-120 mins <input type="checkbox"/> >120 mins		Onset of symptoms from start of administration* <input type="checkbox"/> 1-29 mins <input type="checkbox"/> 30-59 mins <input type="checkbox"/> 60-89 mins <input type="checkbox"/> 90-120 mins <input type="checkbox"/> >120 mins	
Resolution of symptoms within 2 hours?* <input type="checkbox"/> Yes <input type="checkbox"/> No Specify total time to resolution*: _____ min		Resolution of symptoms within 2 hours?* <input type="checkbox"/> Yes <input type="checkbox"/> No Specify total time to resolution*: _____ min	
Medication(s) given for sedation?* <input type="checkbox"/> Yes <input type="checkbox"/> No •If YES, name and dose of medication(s): _____ _____ _____		Medication(s) given for dissociation?* <input type="checkbox"/> Yes <input type="checkbox"/> No •If YES, name and dose of medication(s): _____ _____ _____	

Patient Monitoring Form - Outpatient Use Only

* Indicates Required Field

Patient Information (PRINT)			
First Name*:	MI:	Last Name*:	Birthdate* (MM/DD/YYYY):
			Sex*: <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Other

Healthcare Provider Conducting Patient Monitoring (PRINT)	
First Name*:	Last Name*:
Phone*:	Email:

Serious Adverse Events (PRINT)
<p>A serious adverse event (SAE) for this SPRAVATO[®] REMS is <u>defined</u> as any event that results in/is:</p> <ul style="list-style-type: none"> • Hospitalization • Disability or permanent damage • Death • Life-threatening • Important medical event – defined as any event that may jeopardize the patient or may require intervention to prevent one of the above outcomes

*All non-serious adverse events or product quality complaints that are **not defined above**, should be reported to: Janssen at 1-800-JANSSEN (1-800-526-7736) or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.*

Did the patient experience a serious adverse event?* Yes No If YES, describe below.

Event resulted in the following: (check all that apply)	Event Timing	Event Description (Please list one event per row)	Event Resolution
<input type="checkbox"/> Hospitalization <input type="checkbox"/> Disability or permanent damage <input type="checkbox"/> Death <input type="checkbox"/> Life-threatening <input type="checkbox"/> Important Medical Event	<input type="checkbox"/> During treatment sessions <input type="checkbox"/> Between treatment sessions	_____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
	Date of Event _____ (MM/DD/YYYY)	_____	
<input type="checkbox"/> Hospitalization <input type="checkbox"/> Disability or permanent damage <input type="checkbox"/> Death <input type="checkbox"/> Life-threatening <input type="checkbox"/> Important Medical Event	<input type="checkbox"/> During treatment sessions <input type="checkbox"/> Between treatment sessions	_____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
	Date of Event _____ (MM/DD/YYYY)	_____	
<input type="checkbox"/> Hospitalization <input type="checkbox"/> Disability or permanent damage <input type="checkbox"/> Death <input type="checkbox"/> Life-threatening <input type="checkbox"/> Important Medical Event	<input type="checkbox"/> During treatment sessions <input type="checkbox"/> Between treatment sessions	_____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
	Date of Event _____ (MM/DD/YYYY)	_____	

Janssen Pharmaceuticals, Inc., Safety Department may follow up to obtain more information about these events.