JANSSEN CONNECT
INFORMATION AND ASSISTANCE

Patient Enrollment Form

1 HEALTHCARE PROFESSIONAL (HCP)

HCP Name _____
Facility Name _____
Address _____
_____
Tel ( ) _____ Fax ( ) _____
HCP Email _____

NPI# _____
Facility Contact(s) _____
Facility Contact Tel ( ) _____
Facility Type:
- ☐ Inpatient/Hospital
- ☐ Correctional
- ☐ Outpatient Clinic
- ☐ Telepsychiatry
- ☐ Private Practice
- ☐ Other _____

2 Rx PRESCRIPTION

☐ Check here if a copy of the prescription is attached and sign below

Patient Name _____
Patient Address _____
_____
Tel ( ) _____

DOB ___/___/___ Sex: ☐ Male ☐ Female
Pref. Language: ☐ English ☐ Spanish ☐ Other _____
Diagnosis/ICD Code _____

Is patient new to this medication?
☐ No ☐ Yes

Please list any known drug allergies
_____

INVEGA® SUSTENNA® (paliperidone palmitate) 39mg, 78mg, 117mg, 156mg, 234mg

☐ **Day 1 Dose** _____ mg Qty ____ Date Needed _____
☐ **Day 8 Dose** _____ mg Qty ____ Date Needed _____
☐ **Maintenance Dose** _____ mg Qty ____ Date Needed _____ #Refills: _____
Directions: _____
_____

OR

RISPERDAL® CONSTA® (risperidone) 12.5mg, 25mg, 37.5mg, 50mg

☐ **Dose** _____ mg IM every 2 weeks Qty ____ Date Needed _____ #Refills: _____
Directions: _____
_____

I certify that the above medication is medically necessary and that the information provided is accurate to the best of my knowledge. By my signature I also acknowledge that I have obtained the patient's authorization to release the above information and such other information as may be required by JANSSEN® CONNECT® to provide the offerings selected. I appoint JANSSEN® CONNECT®, on my behalf, to convey this prescription to the dispensing pharmacy of the patient's choice. I further certify that (a) any offering provided through JANSSEN® CONNECT® on behalf of any patient is not made in exchange for any express or implied agreement or understanding that I would recommend, prescribe, or use JANSSEN® CONNECT® or any other product or service for anyone, and that (b) my decision to prescribe the products set forth on this page and request JANSSEN® CONNECT® offerings for my patient was based solely on my determination of medical necessity as set forth herein, and that (c) I will not seek reimbursement for any offering provided by or through JANSSEN® CONNECT® from any government program or third-party insurer.

SIGN HERE

X _____ / / _____
☐ Dispense As Written — Date

X _____ / / _____
☐ Substitution Accepted — Date

X _____ / / _____
Supervising Physician Signature (if applicable) — Date

_____
Supervising Physician Name (print name)

This prescription is only valid if received by fax meeting state regulations.

Comments:

Questions? Call us: 1-877-524-3579
7am to 7pm CT Monday to Friday

FAX: 1-877-785-1124

August 2013 K02JPHA13065

JANSSEN CONNECT® INFORMATION AND ASSISTANCE

Patient Enrollment Form

PATIENT: _____

DOB: __/__/__

3 ALTERNATE PATIENT CONTACT (optional)

This contact information will be used to coordinate care services if the patient cannot be reached or is unable to manage his/her care. See full Patient Authorization Release on page 3 of this enrollment packet for a full description of what may be discussed with the alternate contact listed below.

Name _____ Tel ( ) _____

Relationship to Patient _____

4 INSURANCE

☐ Check here if you're attaching a copy of the insurance card(s)

Primary Insurance Name _____ Tel ( ) _____

Cardholder Name _____ Policy# _____ Group# _____

If patient has a separate prescription coverage plan, please list below

Prescription Plan Name _____ Tel ( ) _____

Policy # _____ Group# _____ Bin# _____ PCN# _____

5 PROGRAM OFFERINGS

Check the box next to the offerings you would like for your patient

A BENEFIT VERIFICATION

☐ Research my patient's Janssen Long-Acting Therapy coverage status

☐ **Prior Authorization Form Assistance:** By checking this, I request that JANSSEN® CONNECT® assist my office in addressing the requirements of this patient's health plan related to prior authorization for treatment with either INVEGA® SUSTENNA® or RISPERDAL® CONSTA®. I understand that assistance may include obtaining the health-plan-specific prior authorization form, and completing it based upon the patient-specific information provided on this form. I understand that the partially completed prior authorization form will be provided to my office by JANSSEN® CONNECT® for possible submission to the health plan.

☐ **Prior Authorization Status Monitoring:** By checking this box, I request that JANSSEN® CONNECT® actively monitor the status of the prior authorization submission. I request that JANSSEN® CONNECT® provide status updates to my office with respect to this.

B PATIENT TRANSITION SUPPORT

☐ Provide information and assistance to help my patient transition to the next healthcare setting

Facility Name _____ Facility Contact _____

Address _____ Tel ( ) _____

_____

☐ Check this box if you would like JANSSEN® CONNECT® to schedule your patient's appointment

C MEDICATION SHIPMENT

☐ Provide assistance in coordinating my patient's medication shipment to my office

☐ Ship to alternate location at: _____

D INJECTION CENTER OPTIONS (if available in your geography)

☐ Fax me a list of available locations

☐ Select a location closest to my patient

☐ Contact my patient to select a location

☐ Use the following approved JANSSEN® CONNECT® location*_____

*By naming the above location, I attest that I do not have a financial relationship with the injection center listed

E REMINDER ALERTS

☐ Contact the following with reminders for injection appts. at my office:

☐ My patient ☐ My patient's alternate contact

My patient's next injection date _____

Questions? Call us: 1-877-524-3579
7am to 7pm CT Monday to Friday

FAX: 1-877-785-1124

August 2013 K02JPHA13065

HIPAA Authorization for JANSSEN® CONNECT®

PATIENT: _____

DOB: ___/___/___

I hereby authorize the use and/or disclosure of my private health information, described below, which includes "Protected Health Information" as defined in federal laws called the Privacy Regulations developed under the Health Insurance Portability and Accountability Act of 1996 (as amended, "HIPAA"). In general terms, I understand that Protected Health Information is health information that identifies me or that could be used to identify me. I understand that this authorization is voluntary.

The following person(s) or class of persons are authorized to disclose this information:

1. Physicians or other healthcare providers that have provided treatment or services to me. I understand that pharmacies that ship my medication may be paid to share this information with JANSSEN® CONNECT® to help provide the offerings requested for me.
2. The company administering JANSSEN® CONNECT®, which at the time of this authorization is United BioSource Corporation (referred to herein as "JANSSEN® CONNECT®")
3. My health plan or other third-party payer.
4. Physicians and other healthcare providers as directed by the healthcare professional enrolling me in JANSSEN® CONNECT®

The following person(s) or class of persons are authorized to receive the information:

1. JANSSEN® CONNECT®.
2. My health plan or other third-party payer.
3. Third parties that assist JANSSEN® CONNECT® with the provision of patient offerings for JANSSEN® CONNECT®.

Description of the information that may be used and/or disclosed:
My diagnosis, prescribed therapy (e.g., INVEGA® SUSTENNA® (paliperidone palmitate) or RISPERDAL® CONSTA® (risperidone)), and a description of the patient offerings I have requested or received from JANSSEN® CONNECT®. I understand that the information disclosed about me may include mental health information and/or records.

The information will be used and/or disclosed for the following purpose(s):

1. For the provision of the JANSSEN® CONNECT® patient offerings requested, such as investigating my prescribed therapy coverage status, assisting with understanding prior authorization or appeal requirements, providing information and assistance to help my transition to my next healthcare setting, assisting in coordinating my medication shipment, helping me

HIPAA Authorization for JANSSEN® CONNECT® (Continued)

PATIENT: _____

DOB: __/__/__

determine additional injection center options, and providing welcome and reminder alerts.

2. In response to a court order, subpoena or otherwise required by law.

Redisclosure: I understand that the Protected Health Information disclosed pursuant to this authorization may be redisclosed by JANSSEN® CONNECT®, for the purposes outlined above, to my health plan(s) or other third-party payer(s), my healthcare providers, JANSSEN® CONNECT® contractors, and any individual I designate as an alternate contact, and I specifically authorize such redisclosures.

Rights and Other Terms:

1. Inability to Condition Treatment, Payment, Enrollment, or Eligibility for Benefits on Provision of Authorization. I understand that my healthcare providers and health plan(s) may not condition my treatment, payment, eligibility for benefits, or enrollment in the health plan upon my signing this authorization.
2. Copy of Authorization. I understand that I am entitled to a signed copy of this authorization.
3. Expiration of Authorization. I understand that this authorization shall expire either when I stop receiving JANSSEN® CONNECT® patient offerings, or 10 years from the date of this authorization, whichever occurs first.
4. Right to Revoke Authorization. I understand that I may revoke (i.e., take back) this authorization at any time except to the extent the recipients of my information have already taken action in reliance on my authorization. To revoke, I understand that I must notify JANSSEN® CONNECT® in writing at the following toll-free fax number: 1-877-785-1124.
5. HIPAA. I understand that the persons who receive my health information pursuant to this authorization may not be required by federal law (such as HIPAA) to protect it, and may share my information with others if permitted by applicable law.
6. Review Information Disclosed. I understand that I have the right to review the information that has been disclosed pursuant to this authorization upon written request to JANSSEN® CONNECT® at the following toll-free fax number: 1-877-785-1124.

By signing this form, I represent that I have read this authorization form and that I understand and agree with what it says.

Patient Name	Legal Authorized Representative Name
SIGN HERE X _____ / /	X _____ / /
Patient Signature Date	Legal Authorized Representative Signature Date

PATIENT: _____

DOB: __/__/__

HIPAA Authorization for Marketing Activities

I have enrolled in the JANSSEN® CONNECT® program and have authorized certain health information about me to be disclosed to the company that administers JANSSEN® CONNECT®, which at the time of this authorization is United BioSource Corporation (referred to herein as "JANSSEN® CONNECT®"). This health information ("Personal Information") includes information about:

- My diagnosis,
- Information about the therapy I have been prescribed (e.g., INVEGA® SUSTENNA® or RISPERDAL® CONSTA®), and
- The patient offerings I have received from JANSSEN® CONNECT®.

This Personal Information may reveal mental-health-related information about me. I now authorize JANSSEN® CONNECT® to use my Personal Information to:

- Send me educational and marketing materials regarding the JANSSEN®CONNECT® program, my prescribed therapy, and other related products or offerings in which I might be interested,
- Contact me to obtain feedback about Janssen Pharmaceuticals, Inc., UBC or other administrator of the program, the JANSSEN® CONNECT® program, and my prescribed therapy,
- Manage and improve the JANSSEN® CONNECT® program, and
- Respond to a court order, subpoena, or as otherwise required by law.

This information and contact may occur by phone, text, email, or postal mail unless I request otherwise from JANSSEN® CONNECT®. I understand that JANSSEN® CONNECT® will only share my Personal Information with third parties who provide support for JANSSEN® CONNECT® pursuant to contracts where those third parties agree to use the information only as described in this authorization, or as required by law or legal process.

I understand that, with respect to this authorization:

- I sign this authorization voluntarily. I understand that I may refuse to sign this authorization.
- I understand that JANSSEN® CONNECT® will receive payment from Janssen Pharmaceuticals, Inc., for providing me with the information and materials described in this authorization.
- I am entitled to a signed copy of this authorization for my records.
- I may revoke this authorization in writing at any time, except to the extent that action has already been taken in reliance upon this authorization, and if not earlier revoked, this authorization will terminate on the sooner of (i) when I stop receiving JANSSEN® CONNECT® patient offerings, or (ii) 10

HIPAA Authorization for Marketing Activities (Continued)

PATIENT: _____

DOB: __/__/__

years from the date of this authorization. To revoke, I understand that I must notify JANSSEN® CONNECT® in writing at the following toll-free fax number: 1-877-785-1124. I understand that any revocation will not apply to information that has already been used and released in response to this authorization.

- The persons who receive my health information pursuant to this authorization may not be required by federal law (such as HIPAA) to protect it, and may share my information with others if permitted by applicable law.
- I understand that I have the right to review any information that has been disclosed pursuant to this authorization upon written request to JANSSEN® CONNECT® at the following toll-free fax number: 1-877-785-1124.

By signing this form, I represent that I have read this authorization form and that I understand and agree with what it says.

SIGN HERE

Patient Name

X _____ / /

Patient Signature Date

Patient Email

Legal Authorized Representative Name

X _____ / /

Legal Authorized Representative Signature Date

HIPAA Authorization for Sharing JANSSEN® CONNECT® Patient Data with Payer

PATIENT: _____

DOB: ___/___/___

I have enrolled in the JANSSEN® CONNECT® program and have authorized certain health information about me to be disclosed to the company that administers JANSSEN® CONNECT®, which at the time of this authorization is United BioSource Corporation (referred to herein as "JANSSEN® CONNECT®"). This health information ("Personal Information") includes information about:

- My diagnosis,
- The therapy prescribed to me (e.g., INVEGA®SUSTENNA® or RISPERDAL® CONSTA®), and
- The patient offerings I have received from JANSSEN® CONNECT®.

This information may reveal mental-health-related information about me. I now hereby authorize JANSSEN® CONNECT® to disclose this Personal Information to my health plan and its affiliates for purposes of:

- My case management and care coordination, and
- The health plan's own data analysis, including to help my health plan to understand how I and others have used the JANSSEN® CONNECT® program, and how the JANSSEN® CONNECT® program has impacted my health care and the care of others participating in the JANSSEN® CONNECT® program and the cost of such health care.

I understand that my health plan may create reports that do not identify me to share with JANSSEN® CONNECT®. I understand that JANSSEN® CONNECT® will not share my Personal Information with any other party for these purposes, except contractors who provide support for JANSSEN® CONNECT® pursuant to contracts where those contractors agree to use the information only as described in this authorization, or as otherwise required by law.

I understand that, with respect to this authorization:

- I sign this authorization voluntarily. I understand that I may refuse to sign this authorization.
- I am entitled to a signed copy of this authorization for my records.
- I may revoke this authorization in writing at any time, except to the extent that action has already been taken in reliance upon this authorization, and if not earlier revoked, this authorization will terminate on the sooner of (i) when I stop receiving JANSSEN® CONNECT® patient offerings, or (ii) 10 years from the date of this authorization. To revoke, I understand that I must notify JANSSEN® CONNECT® in writing at the following toll-free fax number: 1-877-785-1124.

HIPAA authorization for Sharing JANSSEN® CONNECT® Patient Data with Payer (Continued)

PATIENT: _____

DOB: ___/___/___

I understand that any revocation will not apply to information that has already been used and released in response to this authorization.

- The persons who receive my health information pursuant to this authorization may not be required by federal law (such as HIPAA) to protect it, and may share my information with others if permitted by applicable law.
- I understand that I have the right to review any information that has been disclosed pursuant to this authorization upon written request to JANSSEN® CONNECT® at the following toll-free fax number: 1-877-785-1124.

By signing this form, I represent that I have read this authorization form and that I understand and agree with what it says.

Patient Name	Legal Authorized Representative Name
SIGN HERE X _____ / /	X _____ / /
Patient Signature Date	Legal Authorized Representative Signature Date

August 2013

K02JPHA13065

JANSSEN CONNECT® INFORMATION AND ASSISTANCE

Patient Enrollment Form

FAX: 1-877-785-1124

FAX

DATE _____

PAGES _____

SUBJECT JANSSEN® CONNECT® PATIENT ENROLLMENT

FAX # 1-877-785-1124

PHONE # 1-877-524-3579

FROM _____

FAX# _____

Please find the following attached:

- ☐ Page 1.....Healthcare Professional (HCP) Information and Prescription (REQUIRED)
- ☐ Page 2.....Patient Insurance Information and Program Offerings (REQUIRED)
- ☐ Pages 3-4.....HIPAA Authorization for JANSSEN® CONNECT® (REQUIRED)
- ☐ Pages 5-6.....HIPAA Authorization for Marketing Activities
- ☐ Pages 7-8.....HIPAA Authorization for Sharing Patient Data with Payer

INVEGA® SUSTENNA® (paliperidone palmitate) is indicated for the treatment of schizophrenia. Efficacy was established in four short-term studies and one longer-term study in adults.

IMPORTANT SAFETY INFORMATION FOR INVEGA® SUSTENNA® (paliperidone palmitate)

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS.

- Elderly patients with dementia- elated psychosis treated with antipsychotic drugs are at an increased risk of death.
- INVEGA® SUSTENNA® is not app oved for the treatment of patients with dementia-related psychosis.
- *See full Prescribing Information for Warnings and Precautions (5.1).*

Contraindications: Paliperidone is contraindicated in patients with a known hypersensitivity to either paliperidone, risperidone, or to any components of the formulation.

Cerebrovascular Adverse Reactions: Cerebrovascular Adverse Reactions (e.g., stroke, transient ischemic attacks), including fatalities, were reported in placebo-controlled trials in elderly patients with dementia-related psychosis taking oral risperidone, aripiprazole, and olanzapine. The incidence of Cerebrovascular Adverse Reactions was significantly higher than with placebo. INVEGA® SUSTENNA® is not approved for the treatment of patients with dementia-related psychosis.

Neuroleptic Malignant Syndrome (NMS): NMS, a potentially fatal symptom complex, has been reported with the use of antipsychotic medications, including paliperidone. Clinical manifestations include muscle rigidity, fever, altered mental status, and evidence of autonomic instability (see full Prescribing Information). Management should include immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy, intensive symptomatic treatment and close medical monitoring, and treatment of any concomitant serious medical problems.

QT Prolongation: Paliperidone causes a modest increase in the corrected QT (QTc) interval. Avoid the use of drugs that also increase QTc interval and in patients with risk factors for prolonged QTc interval. Paliperidone should also be avoided in patients with congenital long QT syndrome and in patients with a history of cardiac arrhythmias. Certain circumstances may increase the risk of the occurrence of torsades de pointes and/or sudden death in association with the use of drugs that prolong the QTc interval.

Tardive Dyskinesia (TD): TD is a syndrome of potentially irreversible, involuntary, dyskinetic movements that may develop in patients treated with antipsychotic medications. The risk of developing TD and the likelihood that dyskinetic movements will become irreversible are believed to increase with duration of treatment and total cumulative dose, but can develop after relatively brief treatment at low doses. Elderly female patients appeared to be at increased risk for TD, although it is impossible to predict which patients will develop the syndrome. Prescribing should be consistent with the need to minimize the risk of TD (see full Prescribing Information). Discontinue drug if clinically appropriate. The syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn.

Metabolic Changes: Atypical antipsychotic drugs have been associated with metabolic changes that may increase cardiovascular/ cerebrovascular risk. These metabolic changes include hyperglycemia, dyslipidemia, and body weight gain. While all of the drugs in the class have been shown to produce some metabolic changes, each drug has its own specific risk profile.

Hyperglycemia and Diabetes Mellitus: Hyperglycemia and diabetes mellitus, in some cases extreme and associated with ketoacidosis, hyperosmolar coma or death have been reported in patients treated with all atypical antipsychotics (APS). Patients starting treatment with APS who have or are at risk for diabetes mellitus should undergo fasting blood glucose testing at the beginning of and during treatment. Patients who develop symptoms of hyperglycemia during treatment should also undergo fasting blood glucose testing. All patients treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia. Some patients require continuation of antidiabetic treatment despite discontinuation of the suspect drug.

Dyslipidemia: Undesirable alterations have been observed in patients treated with atypical antipsychotics.

Weight Gain: Weight gain has been observed with atypical antipsychotic use. Clinical monitoring of weight is recommended.

Orthostatic Hypotension and Syncope: INVEGA® SUSTENNA® may induce orthostatic hypotension in some patients due to its alpha-blocking activity. INVEGA® SUSTENNA® should be used with caution in patients with known cardiovascular disease, cerebrovascular disease or conditions that would predispose patients to hypotension (e.g., dehydration, hypovolemia, treatment with antihypertensive medications). Monitoring should be considered in patients for whom this may be of concern.

Leukopenia, Neutropenia and Agranulocytosis have been reported with antipsychotics, including paliperidone. Patients with a history of clinically significant low white blood cell count (WBC) or drug-induced leukopenia/neutropenia should have frequent complete blood cell counts during the first few months of therapy. At the first sign of a clinically significant decline in WBC, and in the absence of other causative factors, discontinuation of INVEGA® SUSTENNA® should be considered. Patients with clinically significant neutropenia should be carefully monitored for fever or other symptoms or signs of infection and treated promptly if such symptoms or signs occur. Patients with severe neutropenia (absolute neutrophil count <1000/mm^3) should discontinue INVEGA® SUSTENNA® and have their WBC followed until recovery.

Hyperprolactinemia: As with other drugs that antagonize dopamine D_2 receptors, INVEGA® SUSTENNA® elevates prolactin levels and the elevation persists during chronic administration. Paliperidone has a prolactin-elevating effect similar to risperidone, which is associated with higher levels of prolactin elevation than other antipsychotic agents.

Potential for Cognitive and Motor Impairment: Somnolence, sedation, and dizziness were reported as adverse reactions in subjects treated with INVEGA® SUSTENNA®. INVEGA® SUSTENNA® has the potential to impair judgment, thinking, or motor skills. Patients should be cautioned about performing activities that require mental alertness such as operating hazardous machinery, including motor vehicles, until they are reasonably certain that INVEGA® SUSTENNA® does not adversely affect them.

Seizures: INVEGA® SUSTENNA® should be used cautiously in patients with a history of seizures or with conditions that potentially lower seizure threshold. Conditions that lower seizure threshold may be more prevalent in patients 65 years or older.

Administration: For intramuscular injection only. Care should be taken to avoid inadvertent injection into a blood vessel.

Drug Interactions: Strong CYP3A4 inducers: It may be necessary to increase the dose of INVEGA® SUSTENNA® when a CYP3A4 strong inducer (e.g. carbamazepine, rifampin, St. John's wort) is added. It may be necessary to decrease the dose when a CYP3A4 strong inducer is discontinued.

Pregnancy/Nursing: Patients should be advised to notify their physician if they become pregnant/intend to become pregnant or intend to nurse during treatment with INVEGA® SUSTENNA®.

Commonly Observed Adverse Reactions for INVEGA® SUSTENNA®: The most common adverse reactions in clinical trials in patients with schizophrenia (≥5% and twice placebo) were injection site reactions, somnolence/sedation, dizziness, akathisia and extrapyramidal disorder.

For full Prescribing Information please visit janssencns.com/invegasustenna

K01PM121007

RISPERDAL® CONSTA® (risperidone) long-acting injection is indicated for the treatment of schizophrenia and for the maintenance treatment of Bipolar I Disorder.

IMPORTANT SAFETY INFORMATION FOR RISPERDAL® CONSTA® (risperidone)

WARNING: Increased Mortality in Elderly Patients with Dementia-Related Psychosis Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analyses of 17 placebo-controlled trials (modal duration of 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in the drug-treated patients of between 1.6 to 1.7 times the risk of death in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patients is not clear. RISPERDAL® CONSTA® is not approved for the treatment of patients with dementia-related psychosis.

Contraindications: RISPERDAL® CONSTA® is contraindicated in patients with a known hypersensitivity to the product.

Cerebrovascular Adverse Events (CAEs): CAEs (e.g., stroke, transient ischemia attacks), including fatalities, were reported in placebo-controlled trials in elderly patients with dementia-related psychosis taking oral risperidone. The incidence of CAEs was significantly higher than with placebo. RISPERDAL® CONSTA® is not approved for the treatment of patients with dementia-related psychosis.

Neuroleptic Malignant Syndrome (NMS): NMS, a potentially fatal symptom complex, has been reported with the use of antipsychotic medications. Clinical manifestations include muscle rigidity, fever, altered mental status, and evidence of autonomic instability (see full Prescribing Information). Management should include immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy, intensive symptomatic treatment and close medical monitoring, and treatment of any concomitant serious medical problems.

Tardive Dyskinesia (TD): TD is a syndrome of potentially irreversible, involuntary, dyskinetic movements that may develop in patients treated with antipsychotic medications. The risk of developing TD and the likelihood that dyskinetic movements will become irreversible are believed to increase with duration of treatment and total cumulative dose, but can develop after relatively brief treatment at low doses. Elderly women patients appeared to be at increased risk for TD, although it is impossible to predict which patients will develop the syndrome. Prescribing should be consistent with the need to minimize the risk of TD (see full Prescribing Information). Discontinue drug if clinically appropriate. The syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn.

Metabolic Changes: Atypical antipsychotic drugs have been associated with metabolic changes that may increase cardiovascular/cerebrovascular risk. These metabolic changes include hyperglycemia, dyslipidemia, and body weight gain. While all of the drugs in the class have been shown to produce some metabolic changes, each drug has its own specific risk profile.

Hyperglycemia and Diabetes Mellitus: Hyperglycemia and diabetes mellitus, some cases extreme and associated with ketoacidosis, hyperosmolar coma or death have been reported in patients treated with atypical antipsychotics (APS), including RISPERDAL® CONSTA®. Patients starting treatment with APS who have or are at risk for diabetes mellitus should undergo fasting blood glucose testing at the beginning of and during treatment. Patients who develop symptoms of hyperglycemia should also undergo fasting blood glucose testing. All patients treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia. Monitor glucose regularly in patients with diabetes or at risk for diabetes. Some patients require continuation of anti-diabetic treatment despite discontinuation of the suspect drug.

Dyslipidemia: Undesirable alterations have been observed in patients treated with atypical antipsychotics.

Weight Gain: Weight gain has been observed with atypical antipsychotic use. Clinical monitoring of weight is recommended.

Hyperprolactinemia: As with other drugs that antagonize dopamine D_2 receptors, risperidone elevates prolactin levels and the elevation persists during chronic administration. Risperidone is associated with higher levels of prolactin elevation than other antipsychotic agents.

Orthostatic Hypotension and Syncope: RISPERDAL® CONSTA® may induce orthostatic hypotension associated with dizziness, tachycardia, and in some patients, syncope, especially during the initial dose-titration period. RISPERDAL® CONSTA® should be used with caution in patients with known cardiovascular disease (e.g., heart failure, history of MI or ischemia, conduction abnormalities), cerebrovascular disease or conditions that would predispose patients to hypotension (e.g., dehydration, hypovolemia) and additionally elderly patients with renal or hepatic impairment. Monitoring should be considered in patients for whom this may be of concern.

Leukopenia, Neutropenia and Agranulocytosis have been reported with antipsychotics, including RISPERDAL® CONSTA®. Patients with a history of clinically significant low white blood cell count (WBC) or drug-induced leukopenia/neutropenia should have frequent complete blood cell counts during the first few months of therapy. At the first sign of a clinically significant decline in WBC, and in the absence of other causative factors, discontinuation of RISPERDAL® CONSTA® should be considered. Patients with clinically significant neutropenia should be carefully monitored for fever or other symptoms or signs of infection and treated promptly if such symptoms or signs occur. Patients with severe neutropenia (absolute neutrophil count <1000/mm^3) should discontinue RISPERDAL® CONSTA® and have their WBC followed until recovery.

Potential for Cognitive and Motor Impairment: Somnolence was reported in multiple trials in subjects treated with RISPERDAL® CONSTA®. Since RISPERDAL® CONSTA® has the potential to impair judgment, thinking, or motor skills, patients should be cautioned about operating hazardous machinery, including motor vehicles, until they are reasonably certain that RISPERDAL® CONSTA® does not adversely affect them.

Seizures: RISPERDAL® CONSTA® should be used cautiously in patients with a history of seizures.

Dysphagia: Esophageal dysmotility and aspiration have been associated with antipsychotic drug use. Aspiration pneumonia is a common cause of morbidity and mortality in patients with advanced Alzheimer's dementia. Use cautiously in patients at risk for aspiration pneumonia.

Priapism has been reported. Severe priapism may require surgical intervention.

Thrombotic Thrombocytopenic Purpura (TTP) has been reported.

Administration: For intramuscular injection only. Care should be taken to avoid inadvertent injection into a blood vessel.

Suicide: The possibility of suicide attempt is inherent in schizophrenia or bipolar disorder. Close supervision of high-risk patients should accompany drug therapy.

Increased sensitivity in patients with Parkinson's disease or those with dementia with Lewy bodies has been reported. Manifestations and features are consistent with NMS.

Use RISPERDAL® CONSTA® with caution in patients with conditions and medical conditions that could affect metabolism or hemodynamic responses (e.g., recent myocardial infarction or unstable cardiac disease).

Commonly Observed Adverse Reactions for RISPERDAL® CONSTA®: The most common adverse reactions in clinical trials in patients with schizophrenia (≥5%) were headache, Parkinsonism, dizziness, akathisia, fatigue, constipation, dyspepsia, sedation, weight increase, pain in extremities, and dry mouth. The most common adverse reactions in clinical trials in patients with bipolar disorder were weight increased (5% in monotherapy trial) and tremor and Parkinsonism (≥10% in adjunctive therapy trial).

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For full Prescribing Information please visit janssencns.com/risperdal

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