INVEGA® SAMPLE REQUEST

To receive samples of INVEGA®, just complete this form and return it by fax, email, or mail.

Fax to:	Email to:	Mail To: INVEGA® Sample Fulfillment
1-800-241-6146	janssendtpsupport@synergistix.com	PO Box 2909, Milwaukee, WI 53201

Deliver to:

(Fields with an * are required)

Date of Request:_____ Void after 30 days

The information you provide will be used by JanssenPharmaceuticals, Inc., our affiliates, and our service providers to provide you samples and information about INVEGA® (paliperidone). Our Privacy Policy, which may be found at invega.com/privacy policy, further governs the use of the information you provide. By completing and submitting this form you indicate that you read, understand, and agree to these terms.

***First Name:** ***Last Name:**

***State License Number:** ***Professional Designation:**

Practice Name:

***Address:** ***Suite/Floor/Building:**

(Cannot ship to a PO Box address)

***City:** ***State:** ***Zip:**

***Phone Number:** **Fax Number:**

***E-mail Address:**

1 PLEASE CHECK THE ITEMS YOU WOULD LIKE TO RECEIVE. IF NONE ARE SELECTED, NO ITEMS WILL BE SHIPPED.

INVEGA® (paliperidone) Extended-Release Tablets

- ❑ **INVEGA® 3-mg Tablets,** 4 units, 7 tablets per unit
- ❑ **INVEGA® 6-mg Tablets,** 4 units, 7 tablets per unit
- ❑ **INVEGA® 9-mg Tablets,** 4 units, 7 tablets per unit

I certify that I am a licensed practitioner eligible to receive and prescribe these samples. If I am a Nurse Practitioner or Physician Assistant, I certify that I am authorized and eligible in the state within which I am currently practicing, to request and receive these samples and that in states where required I have my supervising physician's approval to do so. Furthermore, I have requested these samples for the medical, needs of my patients and I acknowledge that they are not for sale, resale, trade, barter, or to be returned for credit, or third-party reimbursement. I understand that either my signature or the signature of a responsible person at the receiving facility is required as a receipt of delivery. I also understand that my name and the sample distribution I receive may be reported as required by state or federal law and may then be made available to the public.

[State of Ohio only: By signing this document, I attest that by requesting shipment of these drug samples, I am in compliance with the State of Ohio ORC 4729.51 (TDDD license) or that the medical practice location meets one of the licensing exemptions as outlined in the regulation or in the addendum provided at the time of this request for samples.]

2 YOU MUST RESPOND IN THE SECTION BELOW.

Neglecting to respond will impact your ability to receive samples.

YES ❑ **NO** ❑ **Does the healthcare provider (HCP) treat or is HCP part of a treatment team caring for patients aged 18 or over with schizophrenia?**

YES ❑ **NO** ❑ **Does the HCP treat or is HCP part of a treatment team caring for patients aged 18 or over with schizoaffective disorder?**

3 SIGN HERE AND COMPLETE.

X_____

Licensed Practitioner's Signature (no signature stamps, please)	Professional Designation (MD, DO, NP, PA, or other)	State License # (if incorrect or missing above)	Date

MID-LEVELS ONLY: Print Practice Specialty Jurisdictional Requirements

Upon receipt of this request, samples will be shipped to you within 10 days.

Rules of this program are subject to change without notification.

For questions regarding this program or if you no longer wish to participate, please call 1-800-240-5746.

Authorized Distributor: JOM Pharmaceutical Services, Inc. / Finished product manufactured by: Janssen Ortho, LLC, Gurabo, PR 00778

Please see accompanying full Prescribing Information, including Boxed WARNING, for INVEGA® (paliperidone).

INDICATION

INVEGA® (paliperidone) extended-release tablets are indicated for the treatment of schizophrenia and for the treatment of schizoaffective disorder as monotherapy and an adjunct to mood stabilizers and/or antidepressant therapy.

IMPORTANT SAFETY INFORMATION FOR INVEGA® (paliperidone)

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

See full prescribing information for complete Boxed Warning.

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. INVEGA® is not approved for use in patients with dementia-related psychosis.

Contraindications: Paliperidone is contraindicated in patients with a known hypersensitivity to paliperidone, risperidone, or to any excipients in INVEGA®.

Cerebrovascular Adverse Events (CAEs): CAEs (eg, stroke, transient ischemia 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 CAEs was significantly higher than with placebo. INVEGA® 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 in association with antipsychotic drugs, including paliperidone.

Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status including delirium, and autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure.

If NMS is suspected, immediately discontinue INVEGA® and provide symptomatic treatment and monitoring.

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 torsade de pointes and/or sudden death in association with the use of drugs that prolong the QTc interval.

Tardive Dyskinesia (TD): TD, a syndrome consisting of potentially irreversible, involuntary, dyskinetic movements, may develop in patients treated with antipsychotic drugs. Although the prevalence of the syndrome appears to be highest among the elderly, especially elderly women, it is impossible to predict which patients will develop the syndrome. Whether antipsychotic drug products differ in their potential to cause tardive dyskinesia is unknown.

The risk of developing TD and the likelihood that it will become irreversible appear to increase with the duration of treatment and the cumulative dose. The syndrome can develop after relatively brief treatment periods, even at low doses. It may also occur after discontinuation. TD may remit, partially or completely, if antipsychotic treatment is discontinued. Antipsychotic treatment itself, however, may suppress (or partially suppress) the signs and symptoms of the syndrome, possibly masking the underlying process. The effect that symptomatic suppression has upon the long-term course of the syndrome is unknown.

If signs and symptoms of TD appear in a patient on INVEGA®, drug discontinuation should be considered. However, some patients may require treatment with INVEGA® despite the presence of the syndrome. In patients who do require chronic treatment, use the lowest dose and the shortest duration of treatment producing a satisfactory clinical response. Periodically reassess the need for continued treatment.

Metabolic Changes: Atypical antipsychotic drugs have been associated with metabolic changes that may increase cardiovascular/cerebrovascular risk. The 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 – Hyperglycemia, some cases extreme and associated with ketoacidosis, hyperosmolar coma, or death has been reported in patients treated with atypical antipsychotics (APS), including INVEGA®. 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. Some patients require continuation of anti-diabetic treatment despite discontinuation of the suspect drug.

Dyslipidemia – Undesirable alterations in lipids 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. When treating adolescent patients with INVEGA®, weight gain should be assessed against that expected with normal growth.

Hyperprolactinemia: As with other drugs that antagonize dopamine D_2 receptors, INVEGA® 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.

Gastrointestinal: INVEGA® should ordinarily not be administered to patients with pre-existing severe gastrointestinal narrowing. Rare instances of obstructive symptoms have been reported in patients with known strictures taking non-deformable formulations. INVEGA® should only be used in patients who are able to swallow the tablet whole.

Orthostatic Hypotension and Syncope: INVEGA® may induce orthostatic hypotension in some patients due to its alpha-blocking activity. INVEGA® should be used with caution in

patients with known cardiovascular disease (eg, heart failure, history of MI or ischemia, conduction abnormalities), cerebrovascular disease or conditions that would predispose patients to hypotension (eg, dehydration, hypovolemia, treatment with anti-hypertensive medications). Monitoring should be considered in patients who are vulnerable to hypotension.

Falls: Somnolence, postural hypotension, motor and sensory instability have been reported with the use of antipsychotics, including INVEGA®, which may lead to falls and, consequently, fractures or other fall-related injuries. For patients, particularly the elderly, with diseases, conditions, or medications that could exacerbate these effects, assess the risk of falls when initiating antipsychotic treatment and recurrently for patients on long-term antipsychotic therapy.

Leukopenia, Neutropenia, and Agranulocytosis have been reported temporally related to antipsychotic agents, including INVEGA®. Agranulocytosis has also been reported. Possible risk factors for leukopenia/neutropenia include pre-existing low white blood cell count (WBC) or drug-induced leukopenia/neutropenia. In patients with a history of a clinically significant low WBC or drug-induced leukopenia/neutropenia, perform a complete blood count (CBC) frequently during the first few months of therapy. Discontinuation should be considered at the first sign of a clinically significant decline in WBC in the absence of other causative factors.

Patients with clinically significant neutropenia should be carefully monitored for fever or other symptoms or signs of infection and treated promptly. Patients with severe neutropenia should discontinue INVEGA® and follow their WBC until recovery.

Potential for Cognitive and Motor Impairment: Somnolence was reported in subjects treated with INVEGA®. INVEGA® 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® does not adversely affect them.

Seizures: INVEGA® 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.

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.

Body Temperature Regulation: Disruption of body temperature regulation has been attributed to antipsychotic agents. Both hyperthermia and hypothermia have been reported in association with INVEGA® use.

Thrombotic Thrombocytopenic Purpura (TTP) has been reported.

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

Drug Interactions: Strong CYP3A4/P-glycoprotein (P-gp) inducers: It may be necessary to increase the dose of INVEGA® when a strong inducer of both CYP3A4 and P-gp (eg, carbamazepine, rifampin, St. John's wort) is co-administered. Conversely, on discontinuation of the strong inducer, it may be necessary to decrease the dose of INVEGA®.

Pregnancy/Nursing: INVEGA® may cause extrapyramidal and/or withdrawal symptoms in neonates with third trimester exposure. Advise patients to notify their healthcare professional if they become pregnant or intend to become pregnant during treatment with INVEGA®. Patients should be advised that there is a pregnancy registry that monitors outcomes in women exposed to INVEGA® during pregnancy. INVEGA® can pass into human breast milk. The benefits of breastfeeding should be considered along with the mother's clinical need for INVEGA® and any potential adverse effects on the breastfed infant from INVEGA® or the mother's underlying condition.

Fertility: INVEGA® may cause a reversible reduction in fertility in females.

Commonly Observed Adverse Reactions: The most commonly observed adverse reactions in clinical trials occurring at an incidence of ≥5% and at least 2 times placebo in the treatment of adults with schizophrenia were extrapyramidal symptoms, tachycardia, and akathisia. The most commonly observed adverse reactions in clinical trials occurring at an incidence of ≥5% and at least 2 times placebo in the treatment of adults with schizoaffective disorder were extrapyramidal symptoms, somnolence, dyspepsia, constipation, weight increase, and nasopharyngitis.

Please click here to read the full Prescribing Information, including Boxed WARNING, for INVEGA®.

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