janssen | PHARMACEUTICAL COMPANIES OF Johnson&Johnson

REQUEST FOR INVEGA® (paliperidone) SAMPLES

PLEASE REVIEW AND COMPLETE THE INFORMATION BELOW
FAX COMPLETED FORM (no cover sheet needed) TO: 1-800-241-6146

Deliver To:

MM#–Call Track #
John Q. Sample, MD
123 Any Street, Suite 200 PO Box 123
Anytown, USA 12345-6789

(Fields with an * are required)

*Phone #: Fax #:
*State License #:

Instructions for Requesting Samples:

- Licensed practitioner listed must sign and date the form
- Fax form to: **1-800-241-6146** OR
  Email to: janssendtpsupport@synergistix.com OR
  Mail to:
  INVEGA® Sample Fulfillment
  PO Box 2909
  Milwaukee, WI 5320

Date of Request: **Void after 30 days**

Please confirm that the information we have listed above is correct and is that of a licensed practitioner eligible to receive and prescribe these samples. If not, please complete here (cannot ship to a PO Box address). The information you provide will be used by Janssen Pharmaceuticals, Inc., our affiliates, and our service providers to provide you with 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.

***Name:** ***Professional Designation:**

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

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

***E-mail:**

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

- ❑ **INVEGA®** (paliperidone) Extended-Release Tablets **3 mg** Qty of 4 units: 7 tabs per unit
- ❑ **INVEGA®** (paliperidone) Extended-Release Tablets **6 mg** Qty of 4 units: 7 tabs per unit
- ❑ **INVEGA®** (paliperidone) Extended-Release Tablets **9 mg** Qty of 4 units: 7 tabs per unit

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 he/she part of a treatment team caring for patients aged 18 or over with schizophrenia?**

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

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.]

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: Priority Solutions International / Finished product manufactured by: Janssen Ortho, LLC, Gurabo, PR 00778
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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 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 torsade 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 women 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. 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 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® 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® and have their WBC followed 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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