IMPROVING THE CONTINUITY OF CARE

For Adults With Schizophrenia on Long-Acting Injectable Antipsychotics

INDICATION

INVEGA SUSTENNA® (paliperidone palmitate) is indicated for the treatment of:

- Schizophrenia in adults.

IMPORTANT SAFETY INFORMATION FOR INVEGA SUSTENNA® (paliperidone palmitate)

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 SUSTENNA® is not approved for use in patients with dementia-related psychosis.

Please see Important Safety Information, including Boxed WARNING, on pages 8-10.

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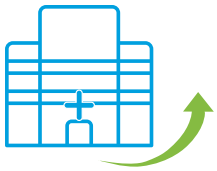
TOO MANY PATIENTS FALL THROUGH THE GAP

With a few simple adjustments in communication and integration between treatment teams, you may be able to help your patients stay on treatment and make a successful transition to outpatient care.



For patients with schizophrenia to stay on treatment and control their symptoms, making a smooth transition from the inpatient setting to an outpatient facility is critical.[1]

Unfortunately, many patients fall through the gap in care. On average, 58% of patients discharged after psychiatric hospitalization fail to attend their first outpatient follow-up visit.[2]

Approximately 1 in 5 adults with a principal diagnosis of schizophrenia at initial stay experienced an all-cause readmission within 30 days.[3*]

*All-cause 30-day readmissions were seen in 19.3% of patients 18-44 years old and 19.7% of patients 45-64 years old. The study did not disclose what medication was received at initial discharge.

Long-acting injectable antipsychotics (LAIs), such as INVEGA SUSTENNA® (paliperidone palmitate), provide the assurance of having medication on board for weeks after administration.[4]

How can you help your patients continue their LAI treatment when transitioning to outpatient care?

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ACTIONABLE BEST PRACTICES (1 of 2)

Consider these tips to address common challenges and help your patients stay on treatment after discharge:

If patients are missing their follow-up appointments:

- **Schedule the date** for the first outpatient injection before discharge
- **Help patients identify an alternate site of care** where they can receive the next injection by visiting **www.JanssenConnectLocator.com or by enrolling the patient in CoverMyMeds®**
- **Ensure the outpatient locations are convenient** and accessible for the patient
- **Provide transportation** for the patient to the outpatient facility
- **Create an outreach plan** for patients who do not follow up
- **Coordinate with a mobile crisis unit** to reestablish contact with patients

If patients are arriving at their first outpatient appointment without insurance coverage for INVEGA SUSTENNA® (paliperidone palmitate):

- While the patient is still in the inpatient setting, verify the patient's insurance benefits for drug coverage in the outpatient setting.
- Once you've made the treatment decision to prescribe INVEGA SUSTENNA®, CoverMyMeds® allows you to complete a benefits verification and provides injection coordination.
- **Involve all the appropriate members of the team** in the discharge process

If you are initiating INVEGA SUSTENNA® and the outpatient appointment is more than 7 days after discharge:

- **Administer both initiation doses** of INVEGA SUSTENNA® while the patient is under your care, with the first dose potentially administered in the emergency room.
  - For initiation dosing information, please see: InvegaSustennaHCP.com/dosing/initiation-and-maintenance
- **Set up flags or pop-ups in your** electronic health records (EHRs) to:
  - Ensure the patient has received both initiation doses of INVEGA SUSTENNA® before discharge
  - Order the second dose of INVEGA SUSTENNA® when the first dose is ordered

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ACTIONABLE BEST PRACTICES (2 of 2)

If the outpatient appointment is with a healthcare professional who does not administer INVEGA SUSTENNA® (paliperidone palmitate):

- **Consult the primary outpatient physician** before starting the LAI to discuss the treatment change and plan for continued injections

- **Ensure the outpatient appointment** is with a healthcare professional who can administer the injection (eg, in addition to a follow-up appointment with a social worker)

If the outpatient healthcare professional does not know what dose of INVEGA SUSTENNA® to administer:

- **Include the dates of the initiation doses** plus the timing and dosage for the next injection on the FIRST PAGE of the discharge papers
  - For initiation and maintenance dosing information, please see: InvegaSustennaHCP.com/dosing/initiation-and-maintenance

- **Establish direct lines of communication** by email or phone between the inpatient and outpatient teams before discharge

- **Communicate dosing information directly** to the outpatient clinic at discharge

If patients are not engaged in their treatment plans:

- **Explain how LAIs can help with their treatment goals** to help patients see the value in continuing treatment

- **Educate patients** before discharge on the importance of continuing care

- **Include family members/caretakers** in the discharge planning process

- **Discuss benefits** and potential adverse events associated with INVEGA SUSTENNA®

What can you do today to help your patients make a smooth transition?

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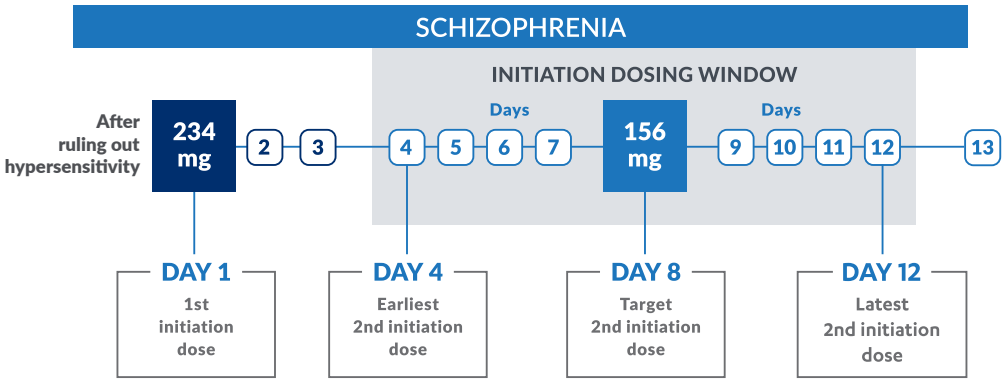
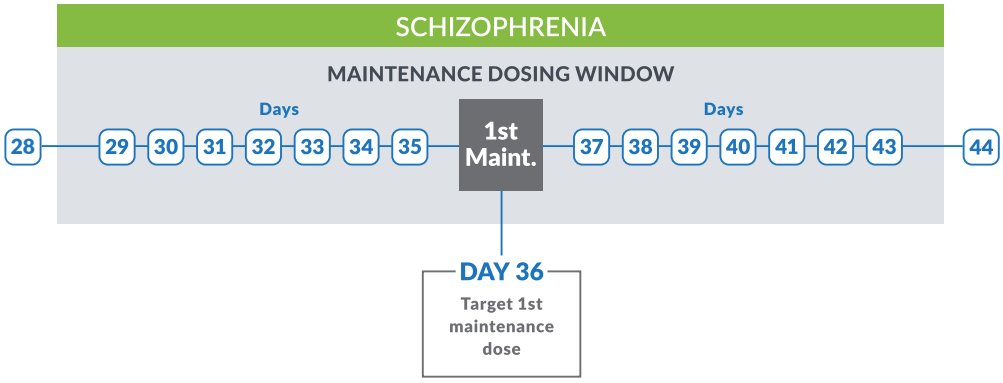
INITIATION & MAINTENANCE DOSING WINDOW FOR INVEGA SUSTENNA®[5]

Initiation Dosing Window



- After the first initiation dose, the second initiation dose should be administered on Day 8
- To avoid a missed dose, patients may be given the second initiation dose within a ±4-day flexible window
- Both initiation doses should be administered in the deltoid muscle

Maintenance Dosing Window



- The first monthly maintenance dose should be administered 5 weeks after the first initiation injection (regardless of the timing of the second initiation injection)
- To avoid a missed dose, monthly maintenance doses may be given within a ±7-day flexible window
  - Utilizing the dosing window to help avoid missed doses should be considered the exception rather than the rule
- The recommended maintenance dose for the treatment of schizophrenia is 117 mg
- Patients may benefit from flexible maintenance dosing options within the available strengths
- Monthly maintenance doses can be administered in either the deltoid or gluteal muscle

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WHAT TO DO IF YOUR PATIENT MISSES A DOSE OF INVEGA SUSTENNA® (paliperidone palmitate)

IF YOUR PATIENT MISSES THE SECOND INITIATION DOSE[5]*

Less than 4 weeks since first injection

Administer the second initiation dose of 156 mg in the deltoid muscle as soon as possible:

1. Administer a third injection of 117 mg in either the deltoid or gluteal muscle 5 weeks after the first injection (regardless of timing of the second injection)
2. Resume regular monthly dosing in either the deltoid or gluteal muscle

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4 to 7 weeks since first injection

Resume dosing with 2 injections of 156 mg:

1. Administer a deltoid injection as soon as possible
2. Administer a second deltoid injection 1 week later
3. Resume regular monthly dosing in either the deltoid or gluteal muscle

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More than 7 weeks since first injection

Restart dosing with normal initiation plan:

1. Administer a 234 mg deltoid injection at day 1
2. Administer a 156 mg deltoid injection 1 week later
3. Resume regular monthly dosing in either the deltoid or gluteal muscle

Refer to section 2.3 Missed Doses in the Prescribing Information for additional information.

IF YOUR PATIENT MISSES A MONTHLY MAINTENANCE DOSE[5]

4 to 6 weeks since last injection

Resume regular dosing as soon as possible at patient's previously stabilized dose, followed by injections at monthly intervals

More than 6 weeks to 6 months since last injection

Continue dosing at patient's previously stabilized dose*:

1. Administer a deltoid injection as soon as possible
2. Administer a second deltoid injection 1 week later at same dose
3. Resume monthly deltoid or gluteal injections at patient's previously stabilized dose 1 month after second dose

*If the patient was stabilized on 234 mg, the first 2 doses should be 156 mg.

More than 6 months since last injection

Restart dosing with normal initiation plan:

1. Administer a 234 mg deltoid injection at day 1
2. Administer a 156 mg deltoid injection 1 week later
3. Resume regular monthly dosing in either the deltoid or gluteal muscle

FOR DOSING ADJUSTMENTS FOR SPECIAL POPULATIONS

View additional missed dose instructions

InvegaSustennaHCP.com/dosing/dose-adjustments

ADDITIONAL RESOURCES TO HELP YOUR PATIENTS STAY ON TREATMENT

To find an alternate site of care, visit the Alternate Site of Care Locator

www.JanssenConnectLocator.com

CoverMyMeds® provides end-to-end patient support in one centralized platform

You can access integrated patient support resources following the prescription to start of therapy, including benefit verification and injection coordination. Learn more at: https://www.covermymeds.com/

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Contraindications: INVEGA SUSTENNA® is contraindicated in patients with a known hypersensitivity to either paliperidone, risperidone, or to any excipients of the INVEGA SUSTENNA® formulation.

Cerebrovascular Adverse Reactions: Cerebrovascular adverse reactions (e.g., stroke, transient ischemic attacks), including fatalities, were reported at a higher incidence in elderly patients with dementia-related psychosis taking risperidone, aripiprazole, and olanzapine compared to placebo. No studies have been conducted with oral paliperidone, INVEGA SUSTENNA®, or the 3-month paliperidone palmitate extended-release injectable suspension in elderly patients with dementia. These medicines are 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 SUSTENNA® 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 torsades de pointes and/or sudden death in association with the use of drugs that prolong the QTc interval.

Tardive Dyskinesia (TD): D, 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 SUSTENNA®, drug discontinuation should be considered. However, some patients may require treatment with INVEGA SUSTENNA® 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. 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-adrenergic 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.

Falls: Somnolence, postural hypotension, motor and sensory instability have been reported with the use of antipsychotics, including INVEGA SUSTENNA®, 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 INVEGA SUSTENNA®. In patients with a history of clinically significant low white blood cell count (WBC)/absolute neutrophil count (ANC) or drug-induced leukopenia/neutropenia, perform a complete blood count frequently during the first few months of therapy. Consider discontinuing INVEGA SUSTENNA® at the first sign of a clinically significant decline in WBC in the absence of other causative factors. Monitor patients with clinically significant neutropenia for fever or other symptoms or signs of infection and treat promptly if such symptoms or signs occur. Discontinue INVEGA SUSTENNA® in patients with severe neutropenia (absolute neutrophil count <1000/mm^3) and follow their WBC 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 by a healthcare professional using only the needles provided in the INVEGA SUSTENNA® kit. Care should be taken to avoid inadvertent injection into a blood vessel.

Drug Interactions: Strong CYP3A4/P-glycoprotein (P-gp) inducers: Avoid using a strong inducer of CYP3A4 and/or P-gp (e.g. carbamazepine, rifampin, St. John's Wort) during a dosing interval for INVEGA SUSTENNA®. If administering a strong inducer is necessary, consider managing the patient using paliperidone extended-release tablets.

Pregnancy/Nursing: INVEGA SUSTENNA® 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 SUSTENNA®. Patients should be advised that there is a pregnancy registry that monitors outcomes in women exposed to INVEGA SUSTENNA® during pregnancy. INVEGA SUSTENNA® can pass into human breast milk. The benefits of breastfeeding should be considered along with the mother's clinical need for INVEGA SUSTENNA® and any potential adverse effects on the breastfed infant from INVEGA SUSTENNA® or the mother's underlying condition.

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.

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cp-64200v3

References: 1. National Council Consensus Statement on the Continuity of Medication Therapy for the Treatment of Schizophrenia. 2006, Dec 6. **2.** Kreyenbuhl J, Nossel IR, Dixon LB. Disengagement from mental health treatment among individuals with schizophrenia and strategies for facilitating connections to care: a review of the literature. *Schizophr Bull*. 2009:35(4):696-703. **3.** Heslin KC, Weiss AJ. Hospital Readmissions Involving Psychiatric Disorders, 2012: Statistical Brief #189. 2015 May. In: Healthcare Cost and Utilization Project (HCUP) Statistical Briefs [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US). **4.** National Council for Mental Wellbeing. Guide to Long-Acting Medications for Providers and Organizations. Published June 5, 2019. Accessed September 20, 2021. https://www.thenationalcouncil.org/topics/long-acting-medications/ **5.** INVEGA SUSTENNA® [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; August 2021.