

# INSTRUCTIONS FOR USE

Please read complete instructions prior to use

For deltoid or gluteal intramuscular injection only



Administer every 3 months<sup>1</sup>



With the syringe tip pointing up, shake syringe vigorously for at least 15 seconds<sup>1</sup>

**For intramuscular injection only.**

**Do not** administer by any other route.



**INVEGA TRINZA<sup>®</sup>**  
paliperidone palmitate extended-release  
injectable suspension  
273 mg, 410 mg, 546 mg, 819 mg

## INDICATION

INVEGA TRINZA<sup>®</sup> (paliperidone palmitate) a 3-month injection, is an atypical antipsychotic indicated for the treatment of schizophrenia in patients after they have been adequately treated with INVEGA SUSTENNA<sup>®</sup> (1-month paliperidone palmitate) for at least four months.

## IMPORTANT SAFETY INFORMATION FOR INVEGA TRINZA<sup>®</sup> (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 TRINZA<sup>®</sup> is not approved for use in patients with dementia-related psychosis.**

Please see Important Safety Information continued on the following pages and [click here](#) to read the full Prescribing Information, including Boxed WARNING, for INVEGA TRINZA<sup>®</sup>.

# IMPORTANT<sup>1</sup>

INVEGA TRINZA® (paliperidone palmitate) should be administered by a healthcare professional as a single injection. **DO NOT** divide dose into multiple injections.

INVEGA TRINZA® is intended for intramuscular use only. Inject slowly, deep into the muscle, taking care to avoid injection into a blood vessel. Read complete instructions prior to use.

## Dosing

This medication should be administered **once every 3 months**.

## Preparation

Peel off tab label from the syringe and place in patient record.

INVEGA TRINZA® requires **longer and more vigorous shaking** than INVEGA SUSTENNA® (1-month paliperidone palmitate extended-release injectable suspension). Shake the syringe vigorously, with the syringe tip pointing up, for **at least 15 seconds within 5 minutes prior to administration** (see Step 2).

## Thin Wall Safety Needle Selection

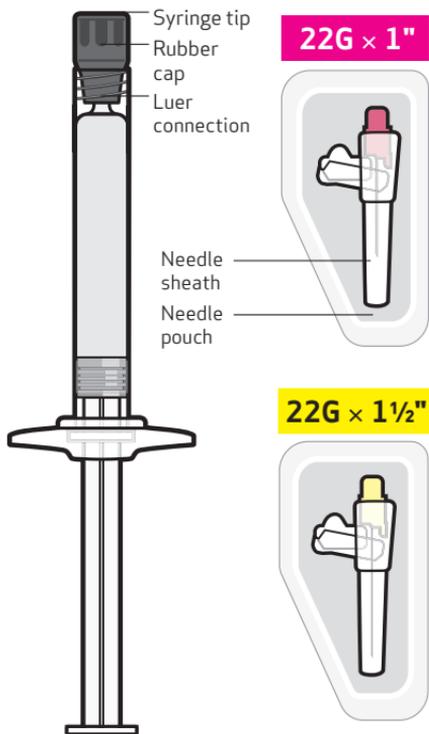
Thin wall safety needles are designed to be used with INVEGA TRINZA®. Therefore, it is important to **only use the needles provided in the INVEGA TRINZA® kit**.

Please see Important Safety Information continued on the following pages and [click here](#) to read the full Prescribing Information, including Boxed WARNING, for INVEGA TRINZA®.

# Dose pack contents<sup>1</sup>

## Each kit contains<sup>1</sup>:

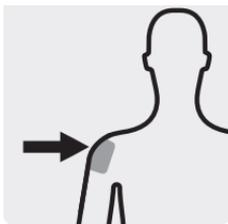
- A prefilled syringe
- 2 thin wall safety needles
  - 22G × 1"
  - 22G × 1½"



## 1 Select needle<sup>1</sup>

Needle selection is determined by injection area and patient weight

If administering a **deltoid** injection



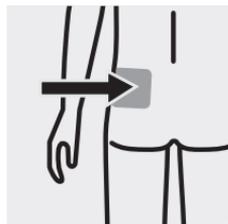
If patient weighs:  
**Less than 90 kg**  
pink hub

**22G × 1"**

**90 kg or more**  
yellow hub

**22G × 1½"**

If administering a **gluteal** injection



If patient weighs:  
**Less than 90 kg**  
yellow hub

**22G × 1½"**

**90 kg or more**  
yellow hub

**22G × 1½"**



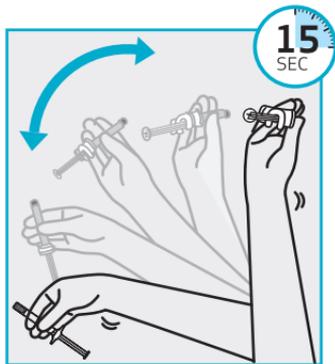
Immediately discard the unused needle in an approved Sharps Container. Do not save for future use.

## 2 Prepare for injection<sup>1</sup>

### SHAKE VIGOROUSLY for at least 15 seconds

With the syringe tip pointing up, SHAKE VIGOROUSLY with a loose wrist for at least 15 seconds to ensure a homogeneous suspension.

**NOTE:** This medication requires longer and more vigorous shaking than the 1-month paliperidone palmitate extended-release injectable suspension.



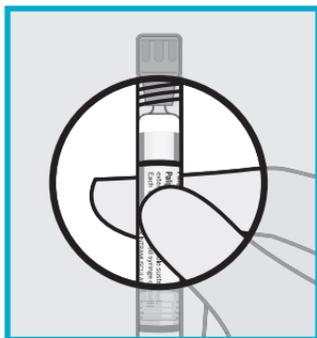
Proceed to the next step immediately after shaking. If more than **5 minutes** pass before injection, shake vigorously, with the syringe tip pointing up, again for at least 15 seconds to resuspend the medication.

### Check suspension

After shaking the syringe for at least 15 seconds, check the liquid in the viewing window.

The suspension should appear uniform and milky white in color.

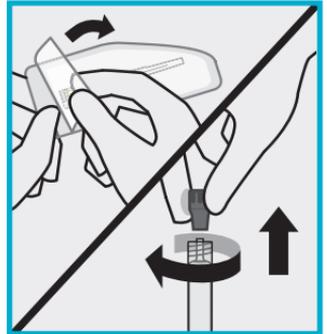
It is also normal to see small air bubbles.



### Open needle pouch and remove cap

First, open needle pouch by peeling the cover back halfway. Place on a clean surface.

Then, holding the syringe upright, twist and pull the rubber cap to remove.



### Grasp needle pouch

Fold back needle cover and plastic tray. Then, firmly grasp the needle sheath through the pouch, as shown.



### Attach needle

With your other hand, hold the syringe by the Luer connection and attach it to the safety needle with a gentle clockwise twisting motion.

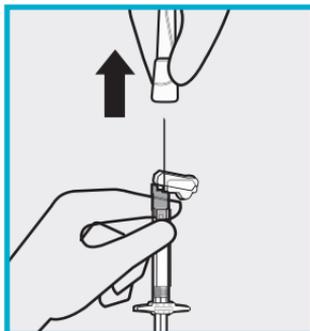
**Do not** remove the pouch until the syringe and needle are securely attached.



### Remove needle sheath

Pull the needle sheath away from the needle in a straight motion.

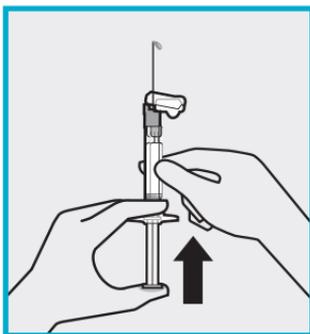
**Do not** twist the sheath, as this may loosen the needle from the syringe.



### Remove air bubbles

Hold the syringe upright and tap gently to make any air bubbles rise to the top.

Remove air by pressing the plunger rod upward carefully until a drop of liquid comes out of the needle tip.

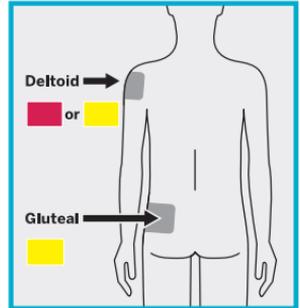


## 3 Inject<sup>1</sup>

### Inject dose

Slowly inject the entire contents of the syringe intramuscularly, deep into the selected deltoid or gluteal muscle.

Do not administer by any other route.

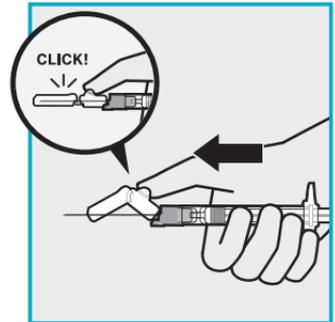


## 4 After injection<sup>1</sup>

### Secure needle

After the injection is complete, use your thumb or a flat surface to secure the needle in the safety device.

The needle is secure when a “click” sound is heard.



### Dispose properly

Dispose of the syringe and unused needle in an approved Sharps Container.



Thin wall safety needles are designed specifically for use with INVEGA TRINZA<sup>®</sup> (paliperidone palmitate). Unused needle should be discarded and not saved for future use.

# IMPORTANT SAFETY INFORMATION

## INDICATION

INVEGA TRINZA® (paliperidone palmitate) a 3-month injection, is an atypical antipsychotic indicated for the treatment of schizophrenia in patients after they have been adequately treated with INVEGA SUSTENNA® (1-month paliperidone palmitate) for at least four months.

## IMPORTANT SAFETY INFORMATION FOR INVEGA TRINZA® (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 TRINZA® is not approved for use in patients with dementia-related psychosis.**

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

Please [click here](#) to read the full Prescribing Information, including Boxed WARNING, for INVEGA TRINZA®.

**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 TRINZA® may induce orthostatic hypotension in some patients due to its alpha-blocking activity. INVEGA TRINZA® 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 TRINZA®, 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 TRINZA® 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  $<1000/\text{mm}^3$ ) should discontinue INVEGA TRINZA® and have their WBC followed until recovery.

**Hyperprolactinemia:** As with other drugs that antagonize dopamine  $D_2$  receptors, INVEGA TRINZA® 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 TRINZA®. INVEGA TRINZA® 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 TRINZA® does not adversely affect them.

**Seizures:** INVEGA TRINZA® 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. Care should be taken to avoid inadvertent injection into a blood vessel.

**Drug Interactions:** Strong CYP3A4/P-glycoprotein (P-gp) inducers: It may be necessary to increase the dose of INVEGA TRINZA® when a strong inducer of both CYP3A4 and P-gp (e.g. carbamazepine, rifampin, St. John's wort) is co-administered. If administering a strong inducer is necessary, consider managing the patient using paliperidone extended release tablets.

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

**Commonly Observed Adverse Reactions for INVEGA TRINZA®:** The most common adverse reactions (incidence  $\geq$  5% and occurring at least twice as often as placebo) were injection site reaction, weight increased, headache, upper respiratory tract infection, akathisia and parkinsonism.

Please [click here](#) to read the full Prescribing Information, including Boxed WARNING, for INVEGA TRINZA®.

**Reference:** 1. INVEGA TRINZA® [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; January 2019.



# INSTRUCTIONS FOR USE

Please read complete instructions prior to use

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Administer every 3 months<sup>1</sup>



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**Do not** administer by any other route.



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Janssen Pharmaceuticals, Inc.

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Janssen  Neuroscience

PHARMACEUTICAL COMPANIES OF 