

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE  
PATIENT MEDICATION INFORMATION**

**PrINVEGA TRINZA®  
paliperidone palmitate Prolonged-Release Injectable Suspension**

Read this carefully before you start taking INVEGA TRINZA® and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about INVEGA TRINZA®.

**Serious Warnings and Precautions**

**Increased Risk of Death in Elderly People with Dementia**

Medicines like INVEGA TRINZA® can raise the risk of death in elderly people who have dementia. INVEGA TRINZA® is not approved for use in patients with dementia.

**What is INVEGA TRINZA® used for?**

INVEGA TRINZA® is used to treat schizophrenia in adults. It is an injection that is given to you once **every 3 months**.

Before you start taking this drug, you will **first** be given INVEGA SUSTENNA®. INVEGA SUSTENNA® contains the same medication as INVEGA TRINZA® and is given once a month. You will get this injection for at least 4 months. Once your symptoms are under control with INVEGA SUSTENNA®, your doctor will switch you to INVEGA TRINZA®. You will be given one injection **every 3 months**.

**How does INVEGA TRINZA® work?**

Dopamine and serotonin are two chemicals that are found in your brain. They are known as neurotransmitters. These two chemicals let the nerve cells in your brain communicate with each other. It is not known exactly how INVEGA TRINZA® works. It seems to help keep the right balance of these two chemicals in your brain.

**What are the ingredients in INVEGA TRINZA® ?**

Medicinal ingredients: paliperidone palmitate

Non-medicinal ingredients: citric acid monohydrate, polyethylene glycol 4000, polysorbate 20, sodium dihydrogen phosphate monohydrate, sodium hydroxide, and water for injection

**INVEGA TRINZA® comes in the following dosage forms:**

Prolonged-Release Injectable Suspension in pre-filled syringes: 175 mg / 0.875 mL, 263 mg / 1.315 mL, 350 mg / 1.75 mL, and 525 mg / 2.625 mL.

**Do not use INVEGA TRINZA® if:**

- you are allergic to paliperidone, risperidone, or to any of the other ingredients in INVEGA TRINZA®.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you start INVEGA TRINZA®. Talk about any health conditions or problems you may have, including if you:**

- have had serious allergic reactions to other medications, including oral risperidone or oral paliperidone. Even if you have not had a reaction to oral paliperidone or risperidone before, it can occur very rarely after receiving injections of INVEGA TRINZA®. Get medical help right away if you experience:
  - a rash
  - swelling in your throat
  - itching
  - problems breathing

These may be signs of a serious allergic reaction.

- are taking RISPERDAL<sup>®</sup> (risperidone)
- have a history of having:
  - a stroke
  - a mini-stroke
  - high cholesterol
  - high blood pressure

Medicines like INVEGA TRINZA<sup>®</sup> can raise the risk of stroke in elderly people with dementia. INVEGA TRINZA<sup>®</sup> is not approved for use in patients with dementia.

- have or have had heart disease or are having a heart disease treatment that makes you more likely to have low blood pressure or feel dizzy when you stand up after sitting or lying down
- have a history of:
  - heart problems
  - any problems with the way your heart beats
- are being treated for high blood pressure
- are taking any medications that affect how your heart beats
- have had neuroleptic malignant syndrome (a disorder that causes you to have high fever and stiffness in your muscles)
- have had tardive dyskinesia (a disorder that causes you to have uncontrolled and repeated movements of the tongue, face or other body parts)
- have or are at risk for diabetes or high blood sugar
- are pregnant, think you may be pregnant, or are planning to become pregnant
- are breast-feeding or are planning to breast-feed
- have had or have prolonged and/or painful erection
- have or have ever had blackouts or seizures
- have or have had low white blood cell count in your blood. Tell your doctor right away if you get a fever or infection while being treated with INVEGA TRINZA<sup>®</sup>
- have high levels of cholesterol or fats (triglycerides) in your blood
- have, have a history of or are at risk of:
  - sleep apnea (a sleep disorder where your breathing is interrupted during sleep)
  - sleep walking
  - sleep-related eating disorder
- have Parkinson's disease or dementia with Lewy bodies (DLB)
- have or have had breast cancer
- have tumours in the pituitary gland
- have a history of kidney problems
- have liver problems
- suffer from Alzheimer's disease
- are feeling thirsty and unwell
- exercise strenuously. This kind of medication may interfere with your body's ability to adjust to heat. You should avoid becoming overheated or dehydrated (for example with vigorous exercise or exposure to extreme heat) while taking INVEGA TRINZA<sup>®</sup>.
- have a fever or infection
- are at risk for developing blood clots. Risk factors include:
  - a family history of blood clots
  - being over the age over 65
  - smoking
  - being overweight
  - having a recent major surgery (such as hip or knee replacement)
  - not being able to move due to air travel or other reasons
  - taking oral birth control ("The Pill")
- are planning to have surgery on your eye(s). During surgery to treat the cloudiness of the lens in your eye(s) (known as cataract surgery):
  - the pupil (the black circle in the middle of your eye) may not increase in size as needed
  - the iris (the coloured part of the eye) may become floppy during surgery. This may lead to eye damage

Tell your eye doctor you are taking this medicine.

## **Other warnings you should know about:**

### **Elderly Patients with Dementia**

- Drugs that contain risperidone (such as RISPERDAL<sup>®</sup>) are similar to drugs that contain paliperidone (such as INVEGA TRINZA<sup>®</sup>). Studies have shown that when risperidone and furosemide (a “water pill”) are taken together by elderly patients who have dementia, it is linked to a higher rate of death.

Tell your doctor if you are taking furosemide. This drug can be used to treat:

- high blood pressure
  - some heart problems
  - swelling of parts of the body caused by the build-up of too much fluid.
- In elderly patients who have dementia, other drugs that belong to the same group of drugs as INVEGA TRINZA<sup>®</sup> have also been linked to side effects that include:
    - a sudden change in mental state
    - sudden weakness or numbness of the face, arms or legs, especially on one side of the body
    - slurred speech
    - vision problems

If you have any of these symptoms, get medical help right away.

### **Effects on newborns**

You should not take INVEGA TRINZA<sup>®</sup> while you are pregnant or if you are planning on becoming pregnant unless you have talked to your doctor about it.

If you took INVEGA TRINZA<sup>®</sup> at any time while you were pregnant or if you took it before you became pregnant, the following symptoms may happen in your newborn baby:

- shaking
- stiffness in their muscles and/or weakness
- sleepiness
- agitation
- breathing problems
- difficulty feeding

Get medical help right away if your newborn baby has any of these symptoms.

In some cases, babies born to a mother who took paliperidone while she was pregnant have had to be hospitalized after experiencing symptoms that were severe.

**Driving and using machines:** Do not drive or operate machinery until you know how you respond to INVEGA TRINZA<sup>®</sup>. Some people experience drowsiness or blurred vision while taking INVEGA TRINZA<sup>®</sup>.

**Falls:** Feeling sleepy, a fall in blood pressure when you stand up from sitting or lying down, vision and speech problems have been reported with the use of antipsychotic drugs. This can lead to falls that may cause fractures or other fall related-injuries. Certain medications, diseases or conditions can make this worse.

**Weight gain:** Weight gain has been seen in patients who are taking antipsychotic drugs. Your doctor may monitor your body weight when you are taking INVEGA TRINZA<sup>®</sup>.

**Blood tests:** Your doctor should do blood tests before you start taking INVEGA TRINZA<sup>®</sup>. They will check your blood sugar levels, and for those with certain risk factors, the level of white blood cells in your blood. Your doctor should continue to check your blood for as long as you are being treated with INVEGA TRINZA<sup>®</sup>.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with INVEGA TRINZA<sup>®</sup> :**

- Alcohol. **Do not** drink alcohol when you are taking INVEGA TRINZA<sup>®</sup>

- Risperidone or oral paliperidone. Taking either of these drugs together with INVEGA TRINZA<sup>®</sup> can increase the amount of paliperidone in your body.
- INVEGA TRINZA<sup>®</sup> can make you feel sleepy or drowsy. You should be careful when you take this drug with other drugs that can also cause you to become sleepy or drowsy.
- Dopamine agonists, (such as levodopa, a drug used to treat Parkinson's disease). Taking this drug may decrease the effects of INVEGA TRINZA<sup>®</sup>. Also, INVEGA TRINZA<sup>®</sup> can affect how drugs used to treat Parkinson's disease work.
- Carbamazepine (a drug used to treat seizures) has been shown to decrease the levels of INVEGA TRINZA<sup>®</sup> in your blood.
- INVEGA TRINZA<sup>®</sup> can lower your blood pressure. You should be careful when you are taking this drug with other drugs that also lower your blood pressure.
- INVEGA TRINZA<sup>®</sup> should be used with caution with medicines that increase the activity of the central nervous system (psychostimulants such as methylphenidate).

This list is not complete and there may be other drugs that can interact with INVEGA TRINZA<sup>®</sup>.

#### **How to take INVEGA TRINZA<sup>®</sup> :**

INVEGA TRINZA<sup>®</sup> is a long-acting medicine that a health care professional will give to you. It is given to you as an injection into your upper arm or buttocks **every 3 months**. This means that you do not have to take it every day. INVEGA TRINZA<sup>®</sup> is designed to release medication slowly over time and provide a steady level of medication over the 3 months.

It is important for you to be treated **first** with INVEGA SUSTENNA<sup>®</sup> (a once a month injection) for at least 4 months before you start taking INVEGA TRINZA<sup>®</sup>. This is so that your doctor can decide if you can safely switch to INVEGA TRINZA<sup>®</sup> and what dose will work best for you.

Your doctor will tell you when you need to come into the doctor's office or clinic for the injection. It is important that you do not miss these appointments. If you cannot make it to your appointment, make sure you call the doctor right away so another appointment can be made as soon as possible.

It is important that you take INVEGA TRINZA<sup>®</sup> exactly how your doctor tells you to.

You should not stop taking this medicine unless your doctor tells you to.

#### **Usual Adult dose:**

Your doctor has decided on the best dose for you based on your needs. Your dose may be changed depending on how you respond to it.

#### **Overdose:**

If you have been given too much INVEGA TRINZA<sup>®</sup>, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Patients who have been given too much paliperidone may experience the following symptoms:

- feeling drowsy or sleepy
- a fast heart rate
- low blood pressure

- irregular heart beat or other symptoms of an irregular heartbeat,, such as lightheadedness or fainting
- unusual movements of the face, body, arms or legs (such as excessive trembling or muscle stiffness)

**Missed Dose:**

If you stop going for your injections, your symptoms may return.

If you cannot keep your appointment with the doctor, make sure you call him/her right away so another appointment can be made as soon as possible. Your doctor or treatment team will decide what you should do next.

**What are possible side effects from using INVEGA TRINZA®?**

These are not all the possible side effects you may feel when taking INVEGA TRINZA®. If you experience any side effects not listed here, contact your healthcare professional.

Side effects include:

- trouble falling asleep or waking up during the night or too early in the morning
- faster heart rate
- slow heart rate
- irregular heartbeat
- stomach ache
- diarrhea
- nausea
- vomiting
- an increase of liver transaminases in your blood
- having low energy
- feeling tired
- headache
- weight gain
- feeling restless
- feeling dizzy
- uncontrollable movements of the face or body
- rigid muscles, slowness of movement and muscle stiffness or spasms
- rash
- high blood pressure
- urinary tract infection
- feeling like you have the flu
- fever
- weight loss
- feeling depressed
- anxiety
- tremors (shaking)
- blurred vision
- dry mouth
- increased saliva
- high blood triglycerides (a fat)
- diabetes or worsening of diabetes
- decreased or increased appetite
- feeling dizzy when you stand up
- drooling
- itching
- feeling pain when you move your eye and problems with moving your eyes
- glaucoma (increased pressure within the eyeball)
- low blood sugar (hypoglycemia).
- lack of bowel muscle movement that causes blockage

- high blood sugar levels (hyperglycemia). See your doctor if you experience symptoms such as excessive thirst or urination.

INVEGA TRINZA® can raise your levels of a hormone called “prolactin” . This is measured with a blood test. Symptoms may include:

- In men:
  - swelling in the breast
  - difficulty in getting or maintain erections or other sexual dysfunction
- In women:
  - discomfort in the breasts
  - leaking of milk from the breasts (even if not pregnant)
  - missing your menstrual period or other problems with your cycle

If you have high levels of prolactin and a condition called hypogonadism you may be at increased risk of breaking a bone due to osteoporosis. This can occur in both men and women.

Since paliperidone is a compound resulting from the breakdown of risperidone in the human body, any side effects that may occur after taking risperidone may also occur with INVEGA TRINZA®.

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>COMMON</b>			
Skin rash on its own		✓	
Swelling or itching at the injection site, injection site pain		✓	
Constipation: new or worsening		✓	
<b>Dystonia:</b> twisting movements that you cannot control, and can affect posture or the face, including eyes, mouth, tongue or jaw		✓	
<b>UNCOMMON</b>			
<b>Severe Allergic Reaction:</b> fever, itching, skin rash, swelling of the mouth, face, lips, or tongue, shortness of breath, and sometimes, a drop in blood pressure (amounting to an “anaphylactic reaction”)			✓
<b>Tardive Dyskinesia:</b> Muscle twitching or abnormal movements of the face or tongue or body		✓	
<b>Decreased White Blood Cells:</b> infections, fatigue, fever, aches, pains, and flu-like symptoms		✓	
Bruise easily, excessive bleeding		✓	
<b>RARE</b>			
A state of confusion, reduced consciousness, high fever, or pronounced muscle stiffness, pain and swelling			✓
Marked changes in body temperature (generally as a result of several factors together including extreme heat or cold)			✓
Seizure (i.e., loss of consciousness with uncontrollable shaking)			✓
Sudden change in mental state or sudden weakness or numbness of the face, arms or			✓

legs, especially on one side, slurred speech or vision problems, even for a short period of time. These symptoms may be associated with stroke.			
Life-threatening complications of uncontrolled diabetes such as shortness of breath, confusion and loss of consciousness			✓
Symptoms of pancreas inflammation such as severe abdominal pain, fever, nausea, vomiting			✓
<b>Blood clots:</b> swelling, pain and redness in an arm or leg that can be warm to touch. You may develop sudden chest pain, difficulty breathing and heart palpitations.		✓	
<b>Dysphagia:</b> difficulty swallowing that can cause food or liquid to get into your lungs		✓	
<b>Catatonia:</b> unable to move or respond while awake		✓	
<b>UNKNOWN</b> Serious Allergic reactions even if you have previously tolerated oral risperidone or oral paliperidone; symptoms include rash, swelling of your throat, itching or problems breathing. These may be signs of a serious allergic reaction			✓
<b>Rhabdomyolysis:</b> very dark (“tea coloured”) urine, muscle tenderness and/or aching			✓
<b>Priapism:</b> long-lasting (greater than 4 hours in duration) and painful erection of the penis			✓
<b>Jaundice:</b> yellowing of the skin and eyes, dark urine			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

### **Reporting Side Effects**

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

#### **3 ways to report:**

- Online at MedEffect ( <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html> ) ;
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program  
Health Canada, Postal Locator 1908C  
Ottawa, ON  
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect ( <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>).

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### **Storage:**

Store INVEGA TRINZA®:

- in its original package
- between 15–30°C.

The expiry date for INVEGA TRINZA® is printed on the package. Do not use the medicine in the package after this date.

Keep out of reach and sight of children.

For questions or concerns, contact the manufacturer, Janssen Inc., [www.janssen.com/canada](http://www.janssen.com/canada) or 1-800-567-3331 or 1-800-387-8781.

This leaflet was prepared by  
Janssen Inc.  
Toronto, Ontario M3C 1L9

Last Revised: September 2018

All trademarks used under license. All other third party trademarks are trademarks of their respective owners.

© 2018 JANSSEN Inc.

NOT FOR DISTRIBUTION OUTSIDE OF CANADA.

This document provides you with the most current information at the time of printing.