

**PART III: CONSUMER INFORMATION**

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

**This leaflet is Part III of a three-part “Product Monograph” published when INVEGA SUSTENNA® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about INVEGA SUSTENNA®. Contact your doctor or pharmacist if you have any questions about the drug.**

**ABOUT THIS MEDICATION**

**What the medication is used for:**  
INVEGA SUSTENNA® belongs to a group of medicines called antipsychotic drugs.

INVEGA SUSTENNA® is a prescription medicine given by injection by a health care professional and used to treat:

- schizophrenia
- schizoaffective disorder

The doctor has prescribed INVEGA SUSTENNA® also known as paliperidone, to help relieve the symptoms that are bothering you/the patient you are caring for. Although INVEGA SUSTENNA® cannot cure the illness, it can keep the symptoms under control and reduce the risk of relapse as you/the patient you are caring for continues treatment.

Not all people with schizophrenia or schizoaffective disorder have the same symptoms. Some of the most common symptoms of schizophrenia and schizoaffective disorder may include:

- hallucinations
  - seeing, feeling, hearing, or smelling things that are not there
- delusions
  - Believing things that are not true
- paranoia
  - Feeling paranoid or not trusting others and feeling very suspicious
- Avoiding family and friends and wanting to be alone

Schizoaffective disorder may also include:

- mania
  - Being very over-active or over-excited
- Symptoms of depression
  - feeling sad, hopeless, helpless, tired, or sleeping a lot or not enough.

**What it does:**  
Antipsychotic medications affect the chemicals that allow communication between nerve cells (neurotransmitters). These chemicals are called dopamine and serotonin. Exactly

how INVEGA SUSTENNA® works is unknown. However, it seems to readjust the balance of dopamine and serotonin.

**When it should not be used:**  
INVEGA SUSTENNA® should not be given if an allergic reaction to the medicine, or a related drug (risperidone), or any of the nonmedicinal ingredients has occurred.

Symptoms of an allergic reaction may include: itching, skin rash, swelling of the face, lips or tongue, shortness of breath. **If you experience any of these symptoms/if these symptoms are experienced by the patient you are caring for, your doctor/the treating physician should be contacted immediately.**

INVEGA SUSTENNA® is not recommended for use in children under 18 years of age.

**What the medicinal ingredient is:**  
Paliperidone palmitate, which is changed into paliperidone after injection.

**What the nonmedicinal ingredients are:**  
Citric acid monohydrate, disodium hydrogen phosphate anhydrous, polyethylene glycol 4000, polysorbate 20, sodium dihydrogen phosphate monohydrate, sodium hydroxide, water for injection.

**What dosage forms it comes in:**  
INVEGA SUSTENNA® (paliperidone palmitate ) Prolonged-Release Injectable Suspension is available in pre-filled syringes in dosage strengths equivalent to: 25 mg†, 50 mg, 75 mg, 100 mg, and 150 mg paliperidone.

†Not currently available in Canada

**WARNINGS AND PRECAUTIONS**

**Serious Warnings and Precautions**  
**Increased Risk of Death in Elderly People with Dementia.** Medicines like INVEGA SUSTENNA® can raise the risk of death in elderly people who have dementia. INVEGA SUSTENNA® is not approved for use in patients with dementia.

BEFORE starting treatment with INVEGA SUSTENNA®, talk to your doctor or pharmacist if you or the patient you are caring for:

- 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 SUSTENNA®
- have a history of stroke, mini-stroke, high cholesterol or high blood pressure. Medicines like INVEGA SUSTENNA® can raise the risk of stroke in elderly people who have dementia. INVEGA SUSTENNA® is not approved for use in patients with dementia.

- 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 or have a family history of diabetes
- 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 a prolonged and/or painful erection
- have or have had a heart disease or heart disease treatment that makes you more likely to have low blood pressure or feeling dizzy or faint when you stand up from lying or sitting positions
- 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 or have ever had blackouts or seizures
- have had low white blood cell counts in your blood. Let your doctor know right away if you develop a fever or infection while being treated with INVEGA SUSTENNA®
- 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/had breast cancer
- have pituitary tumours
- are taking any other medicines (prescription, over-the-counter, or natural health products)
- drink alcoholic beverages or use drugs
- are taking RISPERDAL® (risperidone)
- 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 SUSTENNA®.
- 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 an operation on the 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.

#### **Elderly Patients with Dementia.**

- Drugs that contain risperidone (such as RISPERDAL®) are similar to drugs that contain paliperidone (such as INVEGA SUSTENNA®). 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 SUSTENNA® 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.

- Tell your doctor if you have difficulty swallowing food or have esophageal dysmotility as there is a risk of pneumonia caused by inhaling food.

#### **If you are taking blood pressure medication**

Low blood pressure can result from using INVEGA SUSTENNA® together with medications used to treat high blood pressure. If you need to use both INVEGA

SUSTENNA® and medications used to reduce blood pressure, consult your doctor.

### Effects on newborns

You should not take INVEGA SUSTENNA® 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 SUSTENNA® 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.

### Other cautions

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

**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 SUSTENNA®.

**Blood tests:** Your doctor should do blood tests before you start taking INVEGA SUSTENNA®. 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 SUSTENNA®.

It is important for the doctor to have all the above information before prescribing treatment and dosage. This list should be carefully reviewed by you and discussed with the doctor.

## INTERACTIONS WITH THIS MEDICATION

Inform all doctors, dentists and pharmacists who are treating you or the patient you are caring for that you/the patient you are caring for are/is taking INVEGA SUSTENNA®.

Inform them if you are taking or are planning on taking any other medicine, including prescription, over-the-counter, or natural health products. They will tell you which medicines you can take with INVEGA SUSTENNA®.

Since INVEGA SUSTENNA® works primarily in the brain, interference with other drugs that work in the brain (including alcohol) could occur. It is recommended that you DO NOT drink alcohol and only take drugs prescribed by your doctor.

The following may interact with INVEGA SUSTENNA®:

- Risperidone or oral paliperidone. Taking either of these drugs together with INVEGA SUSTENNA® can increase the amount of paliperidone in your body.
- INVEGA SUSTENNA® 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, e.g., levodopa (a drug used to treat Parkinson's disease), may decrease the effect of INVEGA SUSTENNA®. Also INVEGA SUSTENNA® 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 SUSTENNA® in your blood.
- Since INVEGA SUSTENNA® can lower blood pressure, care should be taken when INVEGA SUSTENNA® is taken with other drugs that lower blood pressure.
- INVEGA SUSTENNA® 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 SUSTENNA®.

## PROPER USE OF THIS MEDICATION

### Usual dose:

INVEGA SUSTENNA® is a long-acting medicine that a health care professional will give to you by injection. This means that you do not have to take this medicine every day.

If you have never before taken INVEGA SUSTENNA®, paliperidone, or risperidone, your doctor will need to make sure you can tolerate the medicine. They will give you a pill form to be taken by mouth daily for a few days before starting INVEGA SUSTENNA®.

When you receive your first dose of INVEGA SUSTENNA® you will need to get a second dose one week later. After that you will only need to get a dose once a month.

If you were previously treated with a long-acting injectable antipsychotic medication and are being switched to INVEGA SUSTENNA<sup>®</sup>, you will only need to get a dose once a month.

Your doctor or health care provider will give you the injection into the muscle of your upper arm or buttocks and will tell you when to come into the doctor's office or clinic for the injection. It is important not to miss your scheduled dose. 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.

The doctor has decided on the best dosage for you based on your needs. Dosage may be increased or decreased depending on the response.

### **Overdose:**

If you have been given too much INVEGA SUSTENNA<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:**

It is important not to miss your scheduled dose. If you stop coming for your injections, your symptoms may return. You should not stop this medicine unless told to do so by your doctor as 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.

If you have any further questions on the use of this product, ask your doctor.

## **SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

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

Side effects that may occur very commonly are headache and trouble falling asleep or waking up during the night or too early in the morning.

Side effects that may occur commonly include: faster heart rate, slow heart rate, stomach ache, constipation, diarrhea, nausea, vomiting, increased liver transaminases in your blood, lack of energy, fatigue, injection site pain, increased weight, feeling of inner restlessness, dizziness, uncontrollable movements of the face or body, rigid muscles, slowness of movement and muscle stiffness or spasm, sleepiness, rash, high blood pressure, urinary tract infection, high blood triglycerides (a fat), feeling like you have the flu, fever, weight loss, depression, anxiety, and tremor (shaking).

INVEGA SUSTENNA<sup>®</sup> 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 getting or maintaining an erection 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 an increased risk of breaking a bone due to osteoporosis. This occurs in both men and women.

High blood sugar has also been reported. See your doctor if you experience symptoms such as excessive thirst or urination.

Uncommon side effects include heartbeat irregularities, blurred vision, dry mouth, increased saliva, diabetes or worsening of diabetes, decreased or increased appetite, seizures, feeling dizzy upon standing, drooling, and itching. While women may experience leakage of fluid or milk from the breast, men may develop breast swelling. Women may experience missed or irregular periods. Men may experience difficulty getting or maintaining an erection.

Let your doctor know right away if you develop a fever or infection while being treated with INVEGA SUSTENNA<sup>®</sup>.

Rare side effects include painful eye movement, problems with the movement of your eyes, and low blood sugar (hypoglycemia).

Lack of bowel muscle movement that causes blockage may occur very rarely.

Side effects where the frequency of occurrence is unknown include glaucoma (increased pressure within the eyeball)

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 SUSTENNA®.

<b>SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM</b>			
Symptom / effect	Call your doctor or pharmacist		Stop taking the drug and seek immediate medical emergency assistance.
	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”)			✓
Seizure (i.e., loss of consciousness with uncontrollable shaking)			✓
<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		✓	
<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)			✓
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.			✓

<b>SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM</b>			
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.		✓	
Bruise easily, excessive bleeding		✓	
<b>Dysphagia:</b> Difficulty swallowing that can cause food or liquid to get into your lungs		✓	
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>Very Rare</b>			
<b>Catatonia:</b> unable to move or respond while awake		✓	
<b>Unknown</b>			
<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			✓
Life-threatening complications of uncontrolled diabetes such as shortness of breath, confusion and loss of consciousness			✓

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.

#### HOW TO STORE IT

Store INVEGA SUSTENNA® in its original package.

INVEGA SUSTENNA® should be stored between 15–30°C.

Keep INVEGA SUSTENNA® out of the reach and sight of children.

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

## 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 0K9Postage 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.*

## MORE INFORMATION

For questions, concerns, or the Product Monograph go to [www.janssen.com/canada](http://www.janssen.com/canada)

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