

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

INVEGA SUSTENNA®

paliperidone palmitate Prolonged-Release Injectable Suspension

Read this carefully before you start taking **INVEGA SUSTENNA®** 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 SUSTENNA®**.

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.

What is INVEGA SUSTENNA® used for?

INVEGA SUSTENNA® is given by your healthcare professional and is used in adults to treat the symptoms of schizophrenia and related psychotic disorders.

Not all people with schizophrenia and related psychotic disorders 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 (not trusting others and feeling very suspicious)
- avoiding family and friends and wanting to be alone

Related psychotic disorders may also include the following symptoms:

- mania (being very over-active and over-excited)
- depression (feeling sad, hopeless, helpless, tired, or sleeping a lot or not enough)

How does INVEGA SUSTENNA® work?

INVEGA SUSTENNA® belongs to a group of medicines called antipsychotic drugs. Antipsychotic medications affect dopamine and serotonin (chemicals found in the brain) that allow for the communication between your nerve cells. Exactly how this medication works is not known. However, it seems that **INVEGA SUSTENNA®** corrects the balance of dopamine and serotonin in your body.

What are the ingredients in INVEGA SUSTENNA® ?

Medicinal ingredients: Paliperidone (as paliperidone palmitate)

Non-medicinal ingredients: Citric acid monohydrate, disodium hydrogen phosphate anhydrous, polyethylene glycol 4000, polysorbate 20, sodium dihydrogen phosphate monohydrate, sodium hydroxide, water for injection.

INVEGA SUSTENNA® comes in the following dosage forms:

Prolonged-Release Injectable Suspension in pre-filled syringes: 50 mg / 0.5 mL, 75 mg / 0.75 mL, 100 mg / 1 mL, and 150 mg / 1.5 mL

Do not use INVEGA SUSTENNA® if:

- you or the person you are caring for has had an allergic reaction to:
 - paliperidone,
 - risperidone (paliperidone is a compound resulting from the breakdown of risperidone in the body) or
 - any of the other ingredients in INVEGA SUSTENNA®

Signs of an allergic reaction include:

- itching
- skin rash
- swelling of the face, lips or tongue
- shortness of breath

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

- are taking or planning to take any other medication (prescription, over-the-counter and natural health products)
 - are taking risperidone
- 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/mini-stroke in elderly people who have dementia.

- 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. INVEGA SUSTENNA® can pass into your breast milk. You should not breast-feed while taking this medication.
- have had or have a prolonged and/or painful erection
- have a history of:
 - heart problems
 - any problems with the way your heart beats
 - congenital long QT syndrome
- are being treated for high blood pressure
- are taking any medications that affect how your heart beats
- are prone to hypotension (low blood pressure), have or have had 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 or have ever had blackouts or seizures

- have or 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 or 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
- drink alcoholic beverages or use drugs
- 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.

Other warnings you should know about:

Elderly Patients with Dementia: Drugs that contain risperidone 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:
 - swelling of parts of the body caused by the build-up of too much fluid
 - some heart problems
 - high blood pressure

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**.

Dysphagia: Tell your doctor if you have difficulty swallowing food or have esophageal dysmotility (problems with your food pipe) as there is a risk of pneumonia caused by inhaling food or liquid that gets into your lungs.

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.

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 do blood tests for as long as you are being treated with INVEGA SUSTENNA®.

The following serious or life-threatening side effects have been reported with similar atypical antipsychotics drugs such as INVEGA SUSTENNA®:

- **Neuroleptic Malignant Syndrome (NMS):**
 - mental changes such as agitation, hallucinations, confusion, or other changes in

- mental status
 - coordination problems, uncontrolled muscle spasms, or muscle twitching (overactive reflexes)
 - restlessness
 - racing or fast heartbeat, high or low blood pressure
 - sweating or fever
 - nausea, vomiting, or diarrhea
 - stiff muscles
- **Severe Skin Reactions:** In very rare cases, skin reactions that can be serious or life-threatening have been reported. This includes skin conditions such as Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS). The following symptoms may be related to these skin reactions:
 - Early warnings for patients:
 - fever
 - severe rash
 - swollen lymph glands
 - flu-like feeling
 - blisters and peeling skin that may start in and around the mouth, nose, eyes and genitals and spread to other areas of the body
 - Later developments:
 - yellow skin or eyes
 - shortness of breath
 - dry cough
 - chest pain or discomfort
 - feeling thirsty
 - urinating less often, less urine

Call your doctor **right away** if you start to have any of the following symptoms while taking INVEGA SUSTENNA®

Tardive Dyskinesia (TD): INVEGA SUSTENNA®, like other antipsychotic medications, can cause potentially irreversible muscle twitching or unusual/abnormal movement of the face or tongue or other parts of your body.

Increased levels of prolactin: INVEGA SUSTENNA® 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 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.

Tell your healthcare professional about all the medications you take, including any

drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with INVEGA SUSTENNA®:

- **DO NOT** drink alcohol and only take medications prescribed by your doctor. Since INVEGA SUSTENNA® works primarily in the brain, interference with other drugs that also work in the brain could occur.
- 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, such as 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 (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 this medicine is taken with other drugs that lower your blood pressure.
- INVEGA SUSTENNA® should be used with caution with medicines that increase the activity of the central nervous system (psychostimulants such as methylphenidate).

How INVEGA SUSTENNA® is given:

INVEGA SUSTENNA® is a long-acting medicine. It will be given to you:

- by your healthcare professional
- as an injection into your muscle (intramuscularly) located on the uppermost part of your arm or in the upper outer side of your buttocks

If you have never taken INVEGA SUSTENNA®, paliperidone, or risperidone before:

- Your doctor will need to make sure you can tolerate the medicine. You will be given the pill form of paliperidone or risperidone to be taken orally (by mouth) everyday for a few days before starting INVEGA SUSTENNA®.
- After your first dose of INVEGA SUSTENNA® you will need to get a second dose 1 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®:

- you will only need to get a dose once a month.

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.

Usual adult dose:

The doctor has decided on the best dosage for you. Your dose may be increased or decreased

depending on:

- other health conditions you may have
- how you respond to the medication

Initiation dose: (given in your upper arm)

On Day 1: 150 mg / 1.5 mL

On Day 8: 100 mg / mL

Maintenance dose: (given either into your upper arm or buttocks)

Once a month: 50 mg / 0.5mL – 150 mg / 1.5 mL

Overdose:

If you think you have been given too much INVEGA SUSTENNA®, 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 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 will decide what you should do next.

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.

What are possible side effects from using INVEGA SUSTENNA®?

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

Side effects include:

- headache
- trouble falling asleep or waking up during the night or too early in the morning.
- faster heart rate
- slow heart rate
- stomach ache
- constipation
- diarrhea
- nausea and vomiting

- lack of energy
- fatigue
- injection site pain
- increased weight
- feeling restless
- dizziness
- uncontrollable movements of the face or body, rigid muscles
- slowness of movement and muscle stiffness or spasm
- feeling sleepy
- rash
- high blood pressure
- urinary tract infection
- high blood triglycerides (a fat)
- feeling like you have the flu
- fever (let your doctor know right away if you develop a fever or infection while on this medication)
- weight loss
- depression
- anxiety
- tremor (shaking)
- low blood sugar, diabetes or worsening of diabetes
 - high blood sugar has been reported; see your doctor if you experience symptoms such as excessive thirst or urination
- heartbeat irregularities
- blurred vision
- dry mouth
- increased saliva
- decreased or increased appetite
- seizures
- feeling dizzy upon standing
- drooling
- itching
- lack of bowel muscle movement that causes blockage (may occur very rarely)
- glaucoma (increased pressure within the eyeball), and problems with the movement of your eyes

Since paliperidone (the ingredient in INVEGA SUSTENNA®) 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®.

| Serious side effects and what to do about them | | | |
|--|--------------------------------------|--------------|----------------------------|
| Symptom / effect | Talk to your healthcare professional | | Get immediate medical help |
| | Only if severe | In all cases | |
| COMMON Skin rash on its own | | ✓ | |
| Swelling or itching at the injection site, injection site pain | | ✓ | |

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| New or worsening constipation | | ✓ | |
| Dystonia: twisting movements that you cannot control, and can affect posture or the face, including eyes, mouth, tongue or jaw | | ✓ | |
| UNCOMMON Severe allergic reactions: fever, difficulty swallowing or breathing, shortness of breath; drop in blood pressure; feeling sick to your stomach and throwing up; hives or rash; swelling of the face, lips, tongue or throat. | | | ✓ |
| Seizure (fits): loss of consciousness with uncontrollable shaking | | | ✓ |
| Tardive Dyskinesia: Muscle twitching or unusual/abnormal movements of the face or tongue or other parts of your body | | ✓ | |
| Leukopenia / Neutropenia (decreased white blood cells): infections, fatigue, fever, aches, pains, and flu-like symptoms | | | ✓ |
| RARE 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) | | | ✓ |
| Stroke: sudden numbness or weakness of your arm, leg or face, especially if only on one side of the body; sudden confusion, difficulty speaking or understanding others; sudden difficulty in walking or loss of balance or coordination; suddenly feeling dizzy or sudden severe headache with no known cause | | | ✓ |
| Pancreatitis (inflammation of pancreas): severe upper abdominal pain, fever, rapid pulse, nausea, vomiting, tenderness when touching the abdomen | | | ✓ |
| Blood clots: 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 | | ✓ | |

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| Dysphagia: 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 | | | ✓ |
| Rhabdomyolysis (breakdown of damaged muscle): muscle tenderness, weakness, red-brown (tea-coloured) urine | | | ✓ |
| VERY RARE Catatonia: unable to move or respond while awake | | ✓ | |
| UNKNOWN Priapism: long-lasting (greater than 4 hours in duration) and painful erection of the penis | | | ✓ |
| Jaundice: yellowing of the skin and eyes, dark urine | | | ✓ |
| Life-threatening complications of uncontrolled diabetes such as shortness of breath, confusion and loss of consciousness | | | ✓ |
| Neuroleptic Malignant Syndrome (NMS): pronounced muscle stiffness or inflexibility with high fever, rapid or irregular heartbeat, sweating, state of confusion or reduced consciousness | | | ✓ |
| Severe skin reactions: fever, severe rash, swollen lymph glands, flu-like feeling, blisters and peeling skin that may start in and around the mouth, nose, eyes and genitals and spread to other areas of the body, yellow skin or eyes, shortness of breath, dry cough, chest pain or discomfort, feeling thirsty, urinating less often, less 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 report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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 SUSTENNA®:

- Between 15-30°C in its original package

Keep out of reach and sight of children.

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

If you want more information about INVEGA SUSTENNA®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website (www.janssen.com/canada), or by calling Janssen Inc. at: 1-800-567-3331 or 1-800-387-8781.

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

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Last Revised: December 17, 2020