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

Studies with various medicines of the group to which INVEGA SUSTENNA® belongs have been associated with an increased rate of death when used in elderly patients with dementia. Some of these studies included treatment with a related drug, RISPERDAL® (risperidone). INVEGA SUSTENNA® is not indicated in elderly 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
- have a history of stroke, mini-stroke, high cholesterol or high blood pressure
- have had neuroleptic malignant syndrome (high temperature and muscle stiffness) or tardive dyskinesia (abnormal movements of the tongue or face)—both of these are conditions caused by antipsychotic drugs
• have or are at risk for diabetes or a family history of diabetes
• are pregnant or planning to become pregnant
• are breast-feeding or planning to breast-feed
• have/had a heart disease or heart disease treatment that makes you prone to 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, or are being treated for high blood pressure
• have/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 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
• have a fever or infection
• have risk factors for developing blood clots such as: a family history of blood clots, age over 65, smoking, obesity, recent major surgery (such as hip or knee replacement), immobility due to air travel or other reasons, or take oral contraceptives (“The Pill”)
• are planning to have an operation on the eye

Elderly Patients with Dementia
Studies in elderly patients with dementia have shown that a related drug, RISPERDAL®, taken by itself or with furosemide, is associated with a higher rate of death (see Serious Warnings and Precautions box).

Tell your doctor if you are taking a furosemide. Furosemide is a drug which is sometimes used to treat high blood pressure, some heart problems, or to treat swelling of parts of the body caused by the build-up of too much fluid.

In elderly patients with dementia, medicines in the same group as INVEGA SUSTENNA® have been associated with side effects including 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. If any of these should occur, even for a short period of time, seek medical attention right away.

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
In some cases, babies born to a mother taking paliperidone during pregnancy have experienced symptoms that are severe and require the newborn to be hospitalized. Sometimes, the symptoms may resolve on their own. Be prepared to seek immediate emergency medical attention for your newborn if they have difficulty breathing, are overly sleepy, have muscle stiffness, or floppy muscles (like a rag doll), are shaking, or are having difficulty feeding.

Other cautions
Very rarely, a state of confusion, reduced consciousness, high fever or stiff muscles might occur. If this should happen, get emergency help right away and tell the doctor that you are receiving INVEGA SUSTENNA®.

During long-term treatment, INVEGA SUSTENNA® might cause involuntary twitching in the face or other body regions. Should this happen, consult your doctor.

Since medications of this type may interfere with the ability of the body to adjust to heat, it is best to avoid becoming overheated or dehydrated (for example with vigorous exercise or exposure to extreme heat) while taking INVEGA SUSTENNA®.

INVEGA SUSTENNA® should be used with caution, and only after consultation with your doctor, if you have heart problems, particularly irregular heart rhythm, abnormalities in electrical activity of the heart, or if you are using medications that can change the heart’s electrical activity.

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

During an operation on the eye for cloudiness of the lens (cataract), the pupil (the black circle in the middle of your eye) may not increase in size as needed. Also, the iris (the colored part of the eye) may become floppy during surgery and that may lead to eye damage. If you are planning to have an operation on your eye, make sure you tell your eye doctor that you are taking this medicine.

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.

- Dopamine agonists, e.g., levodopa (antiparkinsonian agent), may decrease the effect of INVEGA SUSTENNA®.
- Carbamazepine (an anticonvulsant) 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.

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®, 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:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately.

One or more of the following signs may occur in an overdose: sleepiness, drowsiness, tiredness, abnormal body movements, problems with standing and walking, dizziness from low blood pressure, abnormal heart beats, rapid heartbeat, reduced consciousness, and excessive trembling or excessive 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

Like other medications, INVEGA SUSTENNA® can cause side effects. Some side effects are most likely to be minor and temporary. However, some may be serious and need medical attention. Many of the side effects are dose related, so it is important not to exceed your prescribed dose.

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® can raise your levels of a hormone called “prolactin” (measured with a blood test). In men, symptoms of high prolactin may include breast swelling, difficulty in getting or maintaining erections, or other sexual dysfunction. In women, these symptoms may include breast discomfort, leakage of milk from the breasts, missed menstrual periods, or other problems with your cycle.

Weight gain has been observed with INVEGA SUSTENNA® and other atypical antipsychotic medications. Your doctor should check your body weight before starting INVEGA SUSTENNA® and continue to check it for as long as you are being treated.

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®.

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). Your doctor should take blood tests before starting INVEGA SUSTENNA®. They will check blood sugar, and, for those with certain risk factors, the number of infection fighting white blood cells. Your doctor should continue to check your blood for as long as you are being treated.

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 occurs in both men and women.

If you have taken INVEGA SUSTENNA® in the last three months of your pregnancy and you notice that your newborn baby develops shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems or difficulty in feeding, seek immediate emergency medical attention.

During cataract surgery, a condition called intraoperative floppy iris syndrome (IFIS) can happen if you have taken INVEGA SUSTENNA® during the last three months. If you need to have cataract surgery, be sure to tell your eye doctor if you have taken INVEGA SUSTENNA® during the last three months.

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®.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Do not be alarmed by this list of possible side effects. You may not experience any of them. If any of these side effects are experienced, they are usually mild and temporary. However, do not hesitate to report undesired side effects to your doctor.

### Serious Side Effects, How Often They Happen and What to Do About Them

<table>
<thead>
<tr>
<th>Symptom / effect</th>
<th>Call your doctor or pharmacist</th>
<th>Stop taking the drug and seek immediate medical emergency assistance.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skin rash on its own</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Swelling or itching at the injection site, injection site pain</td>
<td>✓</td>
<td></td>
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<tr>
<td>Constipation: new or worsening</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Uncommon</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Allergic reaction: 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”)</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Seizure (i.e., loss of consciousness with uncontrollable shaking)</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Muscle twitching or abnormal movements of the face or tongue</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Marked changes in body temperature (generally as a result of several factors together including extreme heat or cold)</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Decreased White Blood Cells: infections, fatigue, fever, aches, pains, and flu-like symptoms</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Rare</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A state of confusion, reduced consciousness, high fever, or pronounced muscle stiffness, pain and swelling</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Symptoms of pancreas inflammation such as severe abdominal pain, fever, nausea, vomiting</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Bruise easily, excessive bleeding</td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>
SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

<table>
<thead>
<tr>
<th>Side Effect</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>✓</td>
</tr>
<tr>
<td>Rhabdomyolysis symptoms like very dark (“tea coloured”) urine, muscle tenderness and/or aching</td>
<td>✓</td>
</tr>
<tr>
<td>Unknown</td>
<td>✓</td>
</tr>
<tr>
<td>Priapism: long-lasting (greater than 4 hours in duration) and painful erection of the penis.</td>
<td>✓</td>
</tr>
<tr>
<td>Symptoms of jaundice, such as yellowing of the skin and eyes</td>
<td>✓</td>
</tr>
<tr>
<td>Life-threatening complications of uncontrolled diabetes such as shortness of breath, confusion and loss of consciousness.</td>
<td>✓</td>
</tr>
</tbody>
</table>

This is not a complete list of side effects. For any unexpected effects while taking INVEGA SUSTENNA®, contact your doctor or pharmacist.

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 SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
            Health Canada
            Postal Locator 0701E
            Ottawa, Ontario
            K1A OK9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect® Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full Product Monograph, prepared for health professionals can be found at:
http://www.janssen.ca

or by contacting the sponsor, Janssen Inc., at: 1-800-567-3331 or 1-800-387-8781.

This leaflet was prepared by Janssen Inc.
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