

PART III: CONSUMER INFORMATION

INVEGA®
paliperidone Extended-release Tablets

This leaflet is Part III of a three-part “Product Monograph” published when INVEGA® 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®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

INVEGA® belongs to a group of medicines called antipsychotic drugs.

INVEGA® is a prescription medicine used to treat the symptoms of schizophrenia and related psychotic disorders.

The doctor has prescribed INVEGA®, also known as paliperidone, to help relieve the symptoms that are bothering you/the patient you are caring for. Although INVEGA® 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 and related psychotic disorders have the same symptoms. Some of the most common symptoms of schizophrenia and related psychotic disorders 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

Related psychotic disorders 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® works is unknown. However, it seems to readjust the balance of dopamine and serotonin.

When it should not be used:

Do not take/give INVEGA® if you/the patient you are caring for has had an allergic reaction to paliperidone, or a related drug (risperidone), or any of the nonmedicinal ingredients.

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

What the medicinal ingredient is:

Paliperidone

What the nonmedicinal ingredients are:

The following inactive ingredients are common to all tablet strengths: butylated hydroxytoluene, carnauba wax, cellulose acetate, ferric oxide red, ferric oxide yellow, hydroxyethyl cellulose, hypromellose, iron oxide black, polyethylene oxides, polyethylene glycol, povidone, propylene glycol, sodium chloride, stearic acid, and titanium dioxide. The 3 mg tablets also contain lactose monohydrate and triacetin.

What dosage forms it comes in:

Tablets: 3 mg, 6 mg, 9 mg and 12 mg[†].

[†]Not available in Canada

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

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

BEFORE you use INVEGA®, talk to your doctor or pharmacist if you:

- have had serious allergic reactions to other medications, including risperidone
- have a history of stroke, mini-stroke, high cholesterol or high blood pressure. Medicines like INVEGA® can raise the risk of stroke in elderly people who have dementia. INVEGA® 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 a 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 planning to breast feed
- have had or have prolonged and/or painful erection
- 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 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/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®
- 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
- 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”)
- have a narrowing or blockage of your gastrointestinal tract (your esophagus, stomach, or large or small intestine)
- have diseases associated with diarrhea
- have Parkinson’s disease or Dementia with Lewy Bodies (DLB)
- are taking or planning to take any other medicines (prescription or over-the-counter)
- drink alcoholic beverages or use drugs
- suffer from lactose intolerance because INVEGA® tablets contain lactose monohydrate
- are taking RISPERDAL® (risperidone)
- have a history of kidney problems
- have liver problems
- suffer from Alzheimer’s disease
- 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®
- have a fever or infection
- have or have had breast cancer
- have pituitary tumours
- 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.
- are feeling thirsty and unwell

Elderly Patients with Dementia

- Drugs that contain risperidone (such as RISPERDAL®) are similar to drugs that contain paliperidone (such as INVEGA®). 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® 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® 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® 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®. Some people experience drowsiness or blurred vision while taking INVEGA®.

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®.

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

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 that you are taking INVEGA®. 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®.

Since INVEGA® 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®:

- Valproate (drugs used to treat seizures, manic-depression and migraines)
- Risperidone or injectable paliperidone palmitate. Taking either of these drugs together with INVEGA® can increase the amount of paliperidone in your body.
- INVEGA® 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.
- Since INVEGA® can lower blood pressure, care should be taken when INVEGA® is taken with other drugs that lower blood pressure.

- Dopamine agonists, e.g. levodopa (used to treat Parkinson's disease), may decrease the effect of INVEGA®. Also INVEGA® 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® in your blood.
- INVEGA® should be used with caution with medicines that increase the activity of the central nervous system (psychostimulants such as methylphenidate).

PROPER USE OF THIS MEDICATION

Do not chew, crush or divide the tablets. Swallow INVEGA® tablets whole with water or other liquids.

Take INVEGA® once each day preferably in the morning with or without food.

The INVEGA® tablet does not dissolve completely after all the drug has been released, and you may sometimes notice it in your stool. This is normal.

It is very important that you take/give INVEGA® the way the doctor has prescribed it.

The doctor has decided on the best dosage for you/the patient you are caring for based on individual needs. Dosage may be increased or decreased depending on the response.

It is important that you keep taking/giving INVEGA® even after your/the symptoms have improved or disappeared. Do not change or stop taking/giving INVEGA® without consulting the doctor.

DO NOT give INVEGA® to anyone else. The doctor has prescribed it for you/the patient you are caring for.

Usual adult dose:

The usual starting dose is 6 mg once daily.

For patients with impaired kidney function:

Mild impairment: the recommended initial dose is 3 mg once daily; your doctor may later decide to increase the dose to 6 mg once daily.

Moderate to severe impairment: the recommended initial dose is 3 mg every other day; your doctor may later decide to increase the dose to 3 mg once daily.

Overdose:

In case of drug overdose, contact a health care practitioner, 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 miss a dose, do not take a double dose to make up for a forgotten dose.

If you miss one dose, take your next dose on the day following the missed dose.

If you miss two or more doses, contact your doctor.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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

Very commonly headache, or feeling sleepy or less alert may be experienced.

Common side effects may include: common cold symptoms, sinus infection, difficulty falling or staying asleep, mania, irritability, depression, anxiety, faster heart rate, slowed heart rate, heartbeat irregularities, lack of energy, restlessness, feeling dizzy, stuffy nose, drop in blood pressure upon standing, high blood pressure, stomach ache, dry mouth, itching, increased saliva, being sick (vomiting), diarrhea, uncontrollable movements of the face, eyes or body, trembling, slowness of movement, muscle stiffness or spasm, weight gain, and increased appetite.

Uncommon side effects may include: urinary tract infection, feeling like you have the flu, weight loss, anemia, high blood triglycerides (a fat), nightmares, swelling of legs or other body area, increased liver transaminases in your blood, rash, a restless urge to move parts of your body, fainting, sensation the room is spinning, sensation your heart is racing, variation in heart rate, heart rhythm changes, decreased blood pressure, decreased blood flow, rigid muscles, muscle weakness, and joint swelling.

INVEGA® 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.

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

In rare cases, the following may happen: low blood sugar, diabetes mellitus or worsening of diabetes, increased cholesterol, loss of consciousness, heartbeat irregularities, joint stiffness, and vaginal discharge.

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

Side effects where the frequency is not known include glaucoma (increased pressure within the eyeball), and problems with the movement of your eyes.

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®.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom/effect		Call your doctor or pharmacist		Stop taking drug and seek immediate medical emergency help
		Only if severe	In all cases	
Common	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	Skin rash on its own		✓	
	Severe Allergic Reaction: 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 uncontrolled shaking)			✓

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

	Dysphagia: Difficulty swallowing that can cause food or liquid to get into your lungs		✓	
Rare	Rhabdomyolysis: very dark (“tea coloured”) urine, muscle tenderness and/or aching			✓
	Decreased White Blood Cells: infections, fatigue, fever, aches, pains and flu-like symptoms		✓	
	Tardive Dyskinesia: muscle twitching or abnormal movements of the face or tongue or body		✓	
	Strokes and Transient Ischemic Attacks: 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			✓
	Serious Allergic reactions; symptoms include rash, swelling of your throat, itching or problems breathing. These may be signs of a serious allergic reaction			✓
Very Rare	A state of confusion, reduced consciousness, high fever, or pronounced muscle stiffness			✓
	Marked changes in body temperature (generally as a result of several factors together including extreme heat or cold)			✓
	Priapism: Long-lasting (greater than 4 hours in duration) and painful erection of the penis.			✓

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

	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.		✓	
	Catatonia: unable to move or respond while awake		✓	
Unknown	Inflammation of the pancreas: severe abdominal pain, fever, nausea, vomiting			✓
	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			✓
	Bruise easily, excessive bleeding		✓	

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® in its original package.

INVEGA® tablets should be stored between 15–30°C. Protect from moisture.

Keep out of the sight and reach of children.

The expiry date for INVEGA® 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 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.

MORE INFORMATION

For questions, concerns, or the Product Monograph go to www.janssen.com/canada

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