

เอกสารกำกับยาสำหรับผู้ป่วยฉบับภาษาอังกฤษ

INVEGA®

Paliperidone Extended-Release Tablets



WHAT IS INVEGA USED FOR?

Schizophrenia

INVEGA belongs to the class of antipsychotic medicines and is used to treat schizophrenia in adults (18 years of age and older) and adolescents (12-17 years of age). In addition, after symptoms have been relieved, INVEGA is used to keep the disorder under control, i.e. to prevent its recurrence. INVEGA is not for treating people with schizophrenia who are younger than 12 years old.

Schizophrenia is a disorder with symptoms such as hearing things, seeing or sensing things that are not there, mistaken beliefs, unusual suspiciousness, becoming withdrawn, incoherent speech, and reduced behavioral/emotional responses. People with this disorder may also feel depressed, anxious, guilty, or tense.

Bipolar Disorder

INVEGA belongs to the class of antipsychotic medicines and is used to treat adults (18 years of age and older) for manic symptoms of bipolar disorder. INVEGA is not for treating people with bipolar disorder who are younger than 18 years old.

Bipolar disorder is a disorder that includes mania, a mood phase of bipolar disorder which is characterized by symptoms such as elevated or irritable mood, inflated self-esteem, decreased need for sleep, pressured speech, racing thoughts, distractibility or poor judgment including disruptive or aggressive behaviors.

Schizoaffective Disorder

INVEGA belongs to the class of antipsychotic medicines and is used to treat schizoaffective disorder in adults (18 years of age and older), used either alone or with other medicines that are also used to treat depression and/or other mood disorders. INVEGA is not for treating people with schizoaffective disorder who are younger than 18 years old.

Schizoaffective disorder is a mental condition in which a person experiences a combination of schizophrenia symptoms (as listed above) in addition to mood disorder symptoms (feeling very high, feeling sad, feeling agitated, distracted, sleeplessness, talkativeness, losing interest in everyday activities, sleeping too much or too little, eating too much or too little, and recurrent thoughts of suicide).



WHEN NOT TO USE INVEGA

Do not take INVEGA if you know that you are allergic (hypersensitive) to paliperidone or to any of the other ingredients of INVEGA, or to risperidone which is another antipsychotic medicine similar to paliperidone. Hypersensitivity can be recognized for instance by skin rash,

itching, shortness of breath or swollen face. If any of these occur, contact your doctor right away.

WHAT SPECIAL CARE SHOULD YOU TAKE?

Elderly Patients

INVEGA has not been studied in elderly patients with dementia. However, elderly patients with dementia, who are treated with other similar types of medicine, may have an increased risk of stroke or death.

All Patients

If you have any of the following conditions, talk to your doctor as he/she may want to adjust your dose or monitor you for a while.

- if you have Parkinson's disease or Dementia.
- if you have ever been diagnosed with a condition whose symptoms include high temperature and muscle stiffness (also known as Neuroleptic Malignant Syndrome).
- if you have ever experienced abnormal movements of the tongue or face (Tardive Dyskinesia).
- if you are at risk for diabetes or high blood sugar.
- if you have heart disease or heart disease treatment that makes you prone to low blood pressure, or are prone to drop in blood pressure or feeling dizzy when you stand up from lying or sitting positions.
- if you have epilepsy.
- if you 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.
- if you have a swallowing, stomach or intestinal disorder that reduces your ability to swallow or pass food through your digestive system.
- if you have diseases associated with diarrhea.
- if you have a loss of kidney function. Your doctor may reduce your dose of INVEGA if your kidney function is reduced.
- if you have a loss of liver function.
- if you have prolonged and/or painful erection.
- if you have had problems with body temperature regulation.
- if you or someone else in your family has a history of blood clots. Blood clots in the lungs and legs have been seen in patients taking INVEGA. Blood clots in the lungs can be fatal.

Weight gain has been seen in patients receiving antipsychotic medicines. Your doctor may monitor your body weight while you are being treated with INVEGA.

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.



Pregnancy

Tell your doctor if you are pregnant, think you may be pregnant, or are planning to become pregnant. You should not take INVEGA during pregnancy unless this has been discussed with your doctor. Shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, or difficulty in feeding may occur in your newborn baby if you used INVEGA in the last trimester of your pregnancy.



Breastfeeding

Do not breastfeed while you are being treated with INVEGA. Consult your doctor in that case.



Driving or Operating Machinery

INVEGA might affect your alertness and may affect your vision. You are, therefore, advised not to drive or operate machines before you know how sensitive you are to INVEGA.



Other Medicines and Alcohol

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Note that some medicines may increase the levels of paliperidone in your blood, which may produce an increase in side effects resembling overdose of INVEGA. (See OVERDOSE section below.)

Since INVEGA can make you sleepy or drowsy, care should be taken when INVEGA is taken with other medicines that can also cause sleepiness or drowsiness.

Since INVEGA can lower blood pressure, care should be taken when INVEGA is taken with other medicines that lower blood pressure.

INVEGA can reduce the effect of medicines against Parkinson's disease and restless legs syndrome (e.g., levodopa).

INVEGA should be used with caution with medicines that increase the activity of the central nervous system (psychostimulants such as methylphenidate).

Alcohol should be avoided when taking INVEGA.



HOW TO TAKE INVEGA AND HOW MUCH

INVEGA should be taken every morning with or without food. INVEGA must be taken by mouth, swallowed whole with water or other liquids. It must not be chewed, broken, or crushed. The active ingredient, paliperidone, dissolves once swallowed and the tablet shell is passed out of the body as waste. Do not be alarmed if you notice what looks like the INVEGA tablet in your stool.

Always take INVEGA exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

For adults (18 years of age and older) with schizophrenia: The usual dose is 6 mg once a day taken in the morning, but the dose may be increased or decreased by your doctor within the dose range of 3 mg to 12 mg once a day.

For adolescents (12 to 17 years of age) with schizophrenia: The usual dose is 3 mg once a day taken in the morning, but the dose may be increased by your doctor within the range of 6 mg to 12 mg once a day.

For adults (18 years of age and older) with bipolar disorder: The usual dose is 9 mg once a day taken in the morning, but the dose may be increased or decreased by your doctor within the dose range of 3 mg to 12 mg once a day. INVEGA is not approved for treating bipolar disorder in patients younger than 18 years of age.

For adults (18 years of age and older) with schizoaffective disorder: The usual dose is 6 mg once a day taken in the morning, but the dose may be increased or decreased by your doctor within the dose range of 3 mg to 12 mg once a day. INVEGA is not approved for treating schizoaffective disorder in patients younger than 18 years of age.

If you take more INVEGA than you should

Contact your doctor right away. Patients who have taken too much paliperidone may experience the following symptoms: drowsiness or sleepiness, fast heart rate, low blood pressure, an abnormal electrocardiogram (electrical tracing of the heart), or slow or abnormal movements of the face, body, arms, or legs.

If you forget to take INVEGA

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.

If you stop INVEGA

You will lose the effects of the medicine. You should not stop this medicine unless told to do so by your doctor as your symptoms may return.

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

Children and Adolescents

INVEGA is not for treating people with schizophrenia who are younger than 12 years old. INVEGA is not for treating people with bipolar disorder or schizoaffective disorder who are younger than 18 years old.

Patients with kidney or liver impairment

Your doctor may adjust your dose of INVEGA based upon your kidney function. Adjustment in dose based on liver impairment is typically not necessary.



UNDESIRE D EFFECTS

Like all medicines, INVEGA can cause side effects, although not everybody gets them.

Uncommonly, a severe allergic reaction characterized by fever, swollen mouth, face, lip or tongue, shortness of breath, itching, skin rash and sometimes drop in blood pressure (amounting to an 'anaphylactic reaction') can occur. If this occurs, seek medical attention immediately.

In elderly patients with dementia, medicines in the same group as INVEGA have been associated with side effects including sudden weakness or numbness of the face, arms, or legs, instances of slurred speech, or blurred vision. These symptoms may be associated with stroke. If any of these occur, even for a short period of time, seek medical attention immediately.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

Very Common (affects at least 1 patient in 10) may include:

Feeling sleepy or less alert; Headache

Common (affects 1 to 10 patients in 100) may include:

Common cold symptoms; Sinus infection

Weight gain; Increased appetite

Difficulty falling or staying asleep; Elated mood (mania); Irritability; Depression; Anxiety

Parkinsonism (This condition may include slow or impaired movement, sensation of stiffness or tightness of the muscles (making your movements jerky), and sometimes even a sensation of movement "freezing up" and then restarting. Other symptoms of Parkinsonism include a slow shuffling walk, a tremor while at rest, increased saliva and/or drooling, and a loss of expression on the face.)

Dystonia (This is a condition involving slow or sustained involuntary contraction of muscles. While it can involve any part of the body (and may result in abnormal posture), dystonia often involves muscles of the face, including abnormal movements of the eyes, mouth, tongue, or jaw.

Dyskinesia (This is a condition involving involuntary muscle movements, and can include repetitive, spastic, or writhing movements, or twitching)

Restlessness; Dizziness; Problems with speech; Tremor (shaking)

Blurry vision

Abnormal electric conduction of the heart; Prolongation of the QT interval from your heart; Rapid heart rate

Low blood pressure upon standing (consequently, some people taking INVEGA may feel faint, dizzy, or may pass out when they stand up or sit up suddenly); High blood pressure

Cough; Stuffy nose

Abdominal pain or discomfort; Vomiting; Nausea; Constipation; Diarrhea; Indigestion;
Dry mouth; Toothache

Itching

Bone or muscle ache; Back pain

Fever; Weakness; Fatigue (tiredness)

Uncommon (affects 1 to 10 patients in 1000) may include:

Infection of the chest (bronchitis); Infection of the breathing passages; Urinary tract infection;
Ear infection; Tonsillitis; Feeling like you have the flu

Anemia

High blood sugar; Weight loss; Loss of appetite resulting in malnutrition and low body weight;
Increased or decreased appetite; High blood triglycerides (a fat)

Sleep disorder; Inability to reach orgasm; Nightmares

Convulsion (fits); Fainting; A restless urge to move parts of your body; Dizziness upon
standing; Loss or abnormal sense of taste; Reduced sensation of skin to pain and touch

Eye infection or "pink eye"; Dry eye; Increased tears

Ear pain

An interruption in conduction between the upper and lower parts of the heart; Slow heart
rate; Irregular heart beat; Abnormal electrical tracing of the heart (electrocardiogram or ECG);
A fluttering or pounding feeling in your chest (palpitations)

Low blood pressure

Shortness of breath; Wheezing; Sore throat; Nosebleeds

Stomach or intestinal infection; Difficulty swallowing; Excessive passing of gas or wind

Increased liver transaminases in your blood; Increased GGT (a liver enzyme called
gamma-glutamyltransferase in your blood; Increased liver enzymes in your blood

Rash; Dry skin; Acne; Dandruff

An increase of CPK (creatine phosphokinase) in your blood, an enzyme which is sometimes
released with muscle breakdown; Muscle spasms; Joint swelling; Muscle weakness; Neck pain;
Joint pain

Incontinence (lack of control) of urine; Frequent passing of urine; Inability to pass urine;
Pain when passing urine

Erectile dysfunction; Loss of menstrual periods; Leakage of milk from the breasts;
Breast discomfort;

Swelling of the face, mouth, eyes, or lips; Swelling of the body, arms, or legs; An increase in
body temperature; Feeling thirsty; Chest discomfort

Fall

Rare (affects 1 to 10 patients in 10000) may include:

Pneumonia; Bladder infection; Fungal infection of the nails; Infection of the skin; Skin inflammation caused by mites

Decrease in the type of white blood cells that help to protect you against infection; White blood cell count decreased; Decrease in platelets (blood cells that help you stop bleeding); Decrease in red blood cells

Severe allergic reaction characterized by fever, swollen mouth, face, lip, or tongue, shortness of breath, itching, skin rash, and sometimes drop in blood pressure; Allergic reaction

Paliperidone can raise your levels of a hormone called "prolactin" found on a blood test (which may or may not cause symptoms). When symptoms of high prolactin occur, they may include: (in men) breast swelling, difficulty in getting or maintaining erections, or other sexual dysfunction; (in women) breast discomfort, leakage of milk from the breasts, missed menstrual periods, or other problems with your cycle

Dangerously excessive intake of water; Low blood sugar; Diabetes or worsening of diabetes; Increased cholesterol in your blood

Decreased sexual drive

Tardive dyskinesia (twitching or jerking movements that you cannot control in your face, tongue, or other parts of your body). Tell your doctor immediately if you experience involuntary rhythmic movements of the tongue, mouth, and face. Withdrawal of INVEGA may be needed.

Sudden loss of blood supply to brain (stroke or "mini" stroke); Loss of consciousness; Disturbance in attention; A sensation of tingling, pricking, or numbness of skin

Oversensitivity of the eyes to light

Sensation of spinning (vertigo); Ringing in the ears

Atrial fibrillation (an abnormal heart rhythm)

Decreased oxygen in parts of your body (because of decreased blood flow); Flushing

Trouble breathing during sleep (sleep apnea); Fast, shallow breathing

A blockage in the bowels; Swollen tongue; Stool incontinence; Chapped lips

Serious allergic reaction with swelling that may involve the throat and lead to difficulty breathing; Hair loss; Eczema; Skin redness; Skin discoloration

Joint stiffness

Ejaculation disorder; missed menstrual periods or other problems with your cycle (females); Development of breasts in men; Sexual dysfunction; Enlargement of the gland in your breasts; Discharge from the breasts; Vaginal discharge

Chills; A change in the way you walk

Very Rare (affects less than 1 patient in 10000) may include:

Lack of bowel muscle movement that causes blockage

Frequency not known (frequency cannot be estimated from the available data):

Eye infection

Dangerously low numbers of a certain type of white blood cell needed to fight infection in your blood; Increase in eosinophils (a type of white blood cell) in your blood

Inappropriate secretion of a hormone that controls urine volume; Sugar in the urine

Life threatening complications of uncontrolled diabetes; Increased insulin (a hormone that controls blood sugar levels) in your blood; Excessive drinking of water

Confusion; Lack of emotion; Not moving or responding while awake (catatonia); Sleep-related eating disorder; Sleep walking

Neuroleptic malignant syndrome (confusion, reduced or loss of consciousness, high fever, and severe muscle stiffness)

Blood vessel problems in the brain; Unresponsive to stimuli; Low level of consciousness; Coma due to uncontrolled diabetes; Balance disorder; Abnormal coordination; Shaking of the head

Glaucoma (increased pressure within the eyeball); Problems with movement of your eyes; Eye rolling; Redness of the eyes

Eye problems during cataract surgery. During cataract surgery, a condition called intraoperative floppy iris syndrome (IFIS) can happen if you take or have taken INVEGA. If you need to have cataract surgery, be sure to tell your eye doctor if you take or have taken INVEGA.

Rapid heartbeat upon standing

Blood clot in the lungs; Blood clot in the legs

Pneumonia caused by inhaling food; Lung congestion; Congestion of breathing passages; Crackly lung sounds; Voice disorder

Inflammation of the pancreas; Very hard stool

Yellowing of the skin and eyes (jaundice)

Rash on skin related to drug; Hives (or "nettle rash"); Thickening of skin

Severe or life threatening rash with blisters and peeling skin that may start in and around the mouth, nose, eyes, and genitals and spread to other areas of the body (Stevens-Johnson syndrome or toxic epidermal necrolysis)

Breakdown of muscle fibers and pain in muscles (rhabdomyolysis); Abnormal posture

Newborn babies born to mothers who have taken paliperidone during pregnancy may experience side effects of the drug and/or withdrawal symptoms, such as irritability, slow or sustained muscle contractions, shaking, sleepiness, breathing or feeding problems

Priapism (a prolonged penile erection that may require surgical treatment); A delay in menstrual periods; Breast enlargement

Very low body temperature; A decrease on body temperature; Symptoms of drug withdrawal; Feeling unwell; Hardening of the skin



OVERDOSE

In overdose, one or more of the following signs may occur: reduced consciousness, drowsiness, sleepiness, excessive trembling, excessive muscle stiffness, fast beating heart, and low blood pressure. Cases of abnormal electrical conduction in the heart (QT prolongation) and convulsion have been reported. If you experience the above symptoms contact your doctor so you can be treated for taking too much INVEGA.

Information for the Doctor in Case of Overdose

- *Establish and maintain a clear airway if patient has lost consciousness.*
- *Inject sympathomimetic if blood pressure is low.*
- *ECG monitoring is required: consider transfer to hospital.*



HOW TO STORE INVEGA

Do not store above 30°C. Protect from moisture.

Keep out of reach and sight of children.

Do not use INVEGA after the expiry date which is stated on the blister and carton. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.



WHAT IS IN INVEGA?

The actual medicine in INVEGA is paliperidone.

The tablet strengths and descriptions are as follows:

3 mg: white capsule-shaped tablet imprinted with "PAL 3"

6 mg: beige capsule-shaped tablet imprinted with "PAL 6"

9 mg: pink capsule-shaped tablet imprinted with "PAL 9"

The tablets also contain: butyl hydroxytoluene (E321), carnauba wax, cellulose acetate, hydroxyethyl cellulose, hypromellose, iron oxides (E172), polyethylene glycol, polyethylene oxides, povidone, propylene glycol, sodium chloride, stearic acid, and titanium dioxide (E171). The 3 mg tablets also contain lactose monohydrate and triacetin.

Nature and Contents of Container

Blisters: 7 tablets/strip

- Blisters of 3 mg, 6 mg and 9 mg packed in oriented polyamide (OPA)-aluminum-polyvinyl chloride (PVC)/aluminum push-through child-resistant (CR) layer.

Manufacturer: *Janssen-Cilag Manufacturing LLC., Gurabo, Puerto Rico*

Marketing Authorization Numbers and Date of Authorization

Product name	Marketing Authorization Numbers	Date of Authorization
INVEGA (EXTENDED-RELEASE TABLETS, 3 MG)	1C 61/53(N)	31 August 2010
INVEGA (EXTENDED-RELEASE TABLETS, 6 MG)	1C 62/53(N)	31 August 2010
INVEGA (EXTENDED-RELEASE TABLETS, 9 MG)	1C 63/53(N)	31 August 2010

Date of this CPPI: 15 Jan 2024 (CPPI version 07 Apr 2020)

What You Should Know About Medicines

Always inform your doctor or pharmacist if you are using other medicines because some drugs should not be taken together.

Medicines are very well tested before they can be given to patients. There should therefore be little chance of something going wrong if they are used correctly, that is if you use them as follows:

- only for the purpose for which you were given the medicine;*
- only in the recommended amount;*
- only for the recommended period of time.*

Keep all medicines out of the reach of children.

Never allow others to use medicines recommended for you and never use medicines prescribed for others.

Keep all medicines in their original packaging and in a dry place (never in the bathroom, for example!).

Make a habit of returning unused or old medicines to your pharmacist.

If someone has taken an overdose of a medicine, call a doctor or the poison control center

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Janssen-Cilag Ltd., Bangkok, Thailand

To report Suspected Adverse Reactions, please contact us at aepqcjacth@its.jnj.com

For any product information, please contact us at medinfosea@its.jnj.com