

เอกสารกำกับยาสำหรับผู้ป่วยฉบับภาษาอังกฤษ

INVEGA SUSTENNA®

Paliperidone Palmitate Prolonged-Release Suspension for Intramuscular Injection



WHAT IS INVEGA SUSTENNA USED FOR?

INVEGA SUSTENNA belongs to the class of antipsychotic medicines and is used to treat schizophrenia or schizoaffective disorder in adults (18 years of age and older). In addition, after symptoms have been relieved, INVEGA SUSTENNA is used to lessen the chance of your schizophrenia or schizoaffective disorder symptoms from coming back. INVEGA SUSTENNA is not for treating people with schizophrenia or schizoaffective disorder who are younger than 18 years old.

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:

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

Schizoaffective disorder may also include:

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



WHEN NOT TO USE INVEGA SUSTENNA

Do not take INVEGA SUSTENNA if you know that you are allergic (hypersensitive) to paliperidone or to any of the other ingredients of INVEGA SUSTENNA, 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 SUSTENNA 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 SUSTENNA.
- if you have a loss of kidney function. Your doctor may reduce your dose of INVEGA SUSTENNA 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 SUSTENNA. Blood clots in the lungs can be fatal.

Even if you have previously tolerated oral paliperidone or risperidone, very rarely allergic reactions occur after receiving injections of INVEGA SUSTENNA. Seek medical attention right away if you experience a rash, swelling of your throat, itching, or problems breathing as these may be signs of a serious allergic reaction.

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



Pregnancy

Tell your doctor if you are pregnant, think you may be pregnant, or planning to become pregnant. You should not take INVEGA SUSTENNA 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 SUSTENNA in the last trimester of your pregnancy.



Breastfeeding

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



Driving or Operating Machinery

INVEGA SUSTENNA 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 SUSTENNA.



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 SUSTENNA. (See OVERDOSE section below.)

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

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

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

INVEGA SUSTENNA 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 SUSTENNA.



HOW TO TAKE INVEGA SUSTENNA AND HOW MUCH

If you have never before taken INVEGA SUSTENNA, paliperidone, or risperidone, your doctor will need to make sure you can tolerate the medicine by giving you an oral dosage form daily for a few days before starting INVEGA SUSTENNA.

INVEGA SUSTENNA is administered by your doctor or other health care professional in a doctor's office or clinic. Your doctor 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 your doctor right away so another appointment can be made as soon as possible.

INVEGA SUSTENNA will be given by injection into the muscle of your upper arm or buttocks. You will receive the first (150 mg) and second (100 mg) injections of INVEGA SUSTENNA approximately 1 week apart. Thereafter, you will receive an injection (ranging from 25 mg to 150 mg) once a month. Depending on your symptoms, your doctor may increase or decrease the amount of medicine you receive at the time of your scheduled monthly injection.

If you receive more INVEGA SUSTENNA than you should

This medicine will be given to you under medical supervision; it is, therefore, unlikely that you will be given too much.

Patients who have been given 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 stop INVEGA SUSTENNA

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 SUSTENNA is not for treating people with schizophrenia who are younger than 18 years old.

Patients with kidney or liver impairment

Your doctor may adjust your dose of INVEGA SUSTENNA based upon your kidney function. INVEGA SUSTENNA has not been studied in patients with liver impairment, but based on experience with orally-administered paliperidone, adjustment in dose is typically not necessary in patients with mild to moderate liver impairment. The doctor will use his/her best judgement if INVEGA SUSTENNA is being considered for use in a patient with severe liver impairment.



UNDESIRE D EFFECTS

Like all medicines, INVEGA SUSTENNA 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.

Even if you have previously tolerated oral risperidone or oral paliperidone, very rarely allergic reactions occur after receiving injections of INVEGA SUSTENNA. Seek medical attention right away if you experience a rash, swelling of your throat, itching, or problems breathing as these may be signs of a serious allergic reaction.

In elderly patients with dementia, medicines in the same group as INVEGA SUSTENNA 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:

Difficulty falling or staying asleep

Headache

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

Common cold symptoms; Urinary tract infection; Feeling like you have the flu

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

High blood sugar; Weight gain; Weight loss; High blood triglycerides (a fat)

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; Feeling sleepy or less alert; Dizziness; Tremor (shaking)

Slow heart rate; Rapid heart rate

High blood pressure

Cough; Stuffy nose

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

Increased liver transaminases in your blood

Rash

Bone or muscle ache; Back pain

Fever; Weakness; Fatigue (tiredness); A reaction at the injection site, including itching, pain or swelling

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

Pneumonia; Infection of the chest (bronchitis); Infection of the breathing passages; Sinus infection; Bladder infection; Ear infection; Eye infection; Tonsillitis; Infection of the skin; Skin inflammation caused by mites; Abscess under the skin

White blood cell count decreased; Anemia; Decrease in red blood cells; Increase in eosinophils (a type of white blood cell) in your blood

Allergic reaction

Diabetes or worsening of diabetes; Increased insulin (a hormone that controls blood sugar levels) in your blood; Increased appetite; Loss of appetite resulting in malnutrition and low body weight; Decreased appetite; Increased cholesterol in your blood

Sleep disorder; Elated mood (mania); Confusion; Decreased sexual drive; Nightmares

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 SUSTENNA may be needed.

Convulsion (fits); Fainting; A restless urge to move parts of your body; Dizziness upon standing; Disturbance in attention; Problems with speech; Loss or abnormal sense of taste; Reduced sensation of skin to pain and touch; A sensation of tingling, pricking, or numbness of skin

Blurry vision; Eye infection or "pink eye"; Dry eye

Sensation of spinning (vertigo); Ringing in the ears; Ear pain

An interruption in conduction between the upper and lower parts of the heart; Abnormal electrical conduction of the heart; Prolongation of the QT interval from your heart; Rapid heartbeat upon standing; Abnormal electrical tracing of the heart (electrocardiogram or ECG); A fluttering or pounding feeling in your chest (palpitations)

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

Shortness of breath; Lung congestion; Wheezing; Sore throat; Nosebleeds

Stomach or intestinal infection; Dry mouth; Excessive passing of gas or wind

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

Hives (or "nettle rash"); Itching; Hair loss; Eczema; Dry skin; Skin redness; Acne

Muscle spasms; Joint stiffness; Neck pain; Joint pain

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

Erectile dysfunction; Ejaculation disorder; Loss of menstrual periods; A delay in menstrual periods; Missed menstrual periods or other problems with your cycle (females); Development of breasts in men; Leakage of milk from the breasts; Sexual dysfunction; Breast discomfort; Vaginal discharge

Swelling of the face, mouth, eyes, or lips; Swelling of the body, arms or legs; A change in the way you walk; Chest discomfort; Feeling unwell; Hardening of the skin

Fall

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

Fungal infection of the nails

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

Inappropriate secretion of a hormone that controls urine volume

Life threatening complications of uncontrolled diabetes; Low blood sugar; Excessive drinking of water

Not moving or responding while awake (catatonia); Sleep walking

Inability to reach orgasm

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

Sudden loss of blood supply to brain (stroke or "mini" stroke); Unresponsive to stimuli; Loss of consciousness; Low level of consciousness; Balance disorder

Problems with movement of your eyes; Eye rolling; Oversensitivity of the eyes to light; Increased tears; Redness of the eyes

Blood clot in the lungs

Atrial fibrillation (an abnormal heart rhythm); Irregular heart beat

Blood clot in the legs; Flushing

Trouble breathing during sleep (sleep apnea); Congestion of breathing passages

Inflammation of the pancreas; Swollen tongue; Stool incontinence; Very hard stool;
Difficulty swallowing

Rash on skin related to drug; Thickening of skin; Dandruff

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

Inability to pass urine

Enlargement of the glands in your breasts; Breast enlargement; Discharge from the breasts

Priapism (a prolonged penile erection that may require surgical treatment)

Very low body temperature; Chills; An increase in body temperature; Feeling thirsty;
Accumulation of pus caused by infection at injection site; Deep skin infection; A cyst at the injection site; Bruising at injection site

Very Rare (affects less than 1 patient in 10,000) may include:

Allergic reactions even if you have previously tolerated oral paliperidone or risperidone

Lack of bowel muscle movement that causes blockage

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

Dangerously low numbers of a certain type of white blood cell needed to fight infection in your blood

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

Sugar in the urine

Dangerously excessive intake of water

Lack of emotion; sleep related eating disorder

Blood vessel problems in the brain; Coma due to uncontrolled diabetes;
Abnormal coordination

Shaking of the head

Glaucoma (increased pressure within the eyeball)

Eye problems during cataract surgery. 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.

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

Fast, shallow breathing; Pneumonia caused by inhaling food; Crackly lung sounds; Voice disorder

A blockage in the bowels; Chapped lips

Yellowing of the skin and the eyes (jaundice)

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

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

A decrease in body temperature; Symptoms of drug withdrawal; Dead skin cells at injection site; An ulcer at injection site



OVERDOSE

Because INVEGA SUSTENNA is stored and administered by health care professionals, the potential for overdosage by patients is low.

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. Overdose can happen if you are taking other medications together with INVEGA SUSTENNA. If you experience the above symptoms contact your doctor so you can be treated for receiving too much INVEGA SUSTENNA.

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 SUSTENNA

Keep out of reach and sight of children.

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

Do not store above 30°C.

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 SUSTENNA?

The actual medicine in INVEGA SUSTENNA is paliperidone (as paliperidone palmitate).

INVEGA SUSTENNA is available as a white to off-white colored suspension in pre-filled syringes for intramuscular use in the strengths listed below:

39 mg paliperidone palmitate equivalent to 25 mg paliperidone

78 mg paliperidone palmitate equivalent to 50 mg paliperidone

117 mg paliperidone palmitate equivalent to 75 mg paliperidone

156 mg paliperidone palmitate equivalent to 100 mg paliperidone

234 mg paliperidone palmitate equivalent to 150 mg paliperidone

The other ingredients are: citric acid monohydrate, disodium hydrogen phosphate anhydrous, polyethylene glycol 4000, polysorbate 20, sodium dihydrogen phosphate monohydrate, sodium hydroxide (for pH adjustment), water for injection.

Manufacturer: *Janssen Pharmaceutica N.V., Beerse, Kingdom of Belgium*

Marketing Authorization Number

1C 21/54 (N)

Date of Authorization

7 June 2011

Date of this CPPI: 18 Jan 2024 (CPPI version 12-Sep-2022)

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

Imported by

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