

INVEGA[®] EXTENDED RELEASE TABLETS

Paliperidone (3mg, 6mg, 9mg)

What is in this leaflet

1. What INVEGA[®] is used for
2. How INVEGA[®] works
3. Before you use INVEGA[®]
4. How to use INVEGA[®]
5. While you are using it
6. Side effects
7. Storage and Disposal of INVEGA[®]
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What INVEGA[®] is 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). In addition, after symptoms have been relieved, INVEGA[®] is used to keep the disorder under control, i.e. to prevent its recurrence.

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such as hearing things, seeing or sensing things that are not there, mistaken beliefs, unusual suspiciousness, becoming withdrawn, incoherent speech, and reduced behavioral/emotional responses.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.

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).

How INVEGA[®] works

INVEGA[®] can help alleviate the symptoms of your disease and stop your symptoms from coming back.

Before you use INVEGA[®]

- When you must not use it

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.

- Before you start to use it

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 have or are at risk of having diabetes (e.g. being overweight or have family history of diabetes). Your doctor should check your blood sugar before you start taking INVEGA[®] and regularly during treatment.
- 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.

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.

- Taking 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 *If you use too much (overdose)* 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 much to use

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 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.

- When to use it

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.

- How long to use it

Continue taking INVEGA® for as long as your doctor recommends.

- If you forget to use it

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.

- If you use too much (overdose)

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.

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.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking INVEGA®.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give INVEGA® to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of
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®.

Side 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.

Talk to your doctor or pharmacist if you experience:

- increase in blood sugar level and/or symptoms of high blood sugar (e.g. increased hunger, and frequent urination)
- unpleasant leg sensations and an intense urge to move the legs (restless legs syndrome)
- trouble breathing during sleep (sleep apnoea)
- difficulty or inability to pass urine (urinary retention)

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)

There are other possible side effects of INVEGA®. For more information, ask your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI)

Storage and Disposal of INVEGA®

- Storage

Keep out of the sight and reach of children.

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

Bottles: Do not store above 30°C.

Keep the bottle tightly closed in order to protect from moisture.

Blisters: Do not store above 30°C.

Store in the original package in order to protect from moisture.

- Disposal

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.

Product Description

- What it looks like

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"

- Ingredients

- Active ingredient

The actual medicine in INVEGA® is paliperidone.

- Inactive ingredients

The tablets also contain: butylated hydroxytoluene, carnauba wax, cellulose acetate, hydroxyethyl cellulose, ink water-based black, iron oxides, polyethylene glycol, polyethylene oxides, povidone, sodium chloride and stearic acid.

The 9 mg tablets also contain color overcoating material pink.

The 6 mg tablets also contain color overcoating material beige.

The 3 mg tablets also contain color overcoating material white.

- MAL numbers

MAL20081766AZ

MAL20081767AZ

MAL20081768AZ

Manufacturer

Janssen Cilag Manufacturing LLC
State Road 933, Km. 0.1,
Mamey Ward
Gurabo, Puerto Rico 00778
United States

Product Registration Holder

Johnson & Johnson Sdn Bhd (3718-D)
Level 8, The Pinnacle,
Persiaran Lagoon, Bandar Sunway,
46150, Petaling Jaya, Selangor,
Malaysia

Date of revision

09/02/2023 (MYPI vMay2018)

Serial Number

NPRA (R1/2) 09022023/036