Package leaflet: Information for the user

INVEGA 3 mg prolonged-release tablets
INVEGA 6 mg prolonged-release tablets
INVEGA 9 mg prolonged-release tablets

Paliperidone

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What INVEGA is and what it is used for
2. What you need to know before you take INVEGA
3. How to take INVEGA
4. Possible side effects
5. How to store INVEGA
6. Contents of the pack and other information

1. What INVEGA is and what it is used for

INVEGA contains the active substance paliperidone which belongs to the class of antipsychotic medicines.

INVEGA is used to treat schizophrenia in adults and in adolescents aged 15 years and older.

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such as hearing things, seeing or sensing things that are not there, mistaken beliefs, unusual suspiciousness, becoming withdrawn, incoherent speech, and behaviour and emotional flatness. People with this disorder may also feel depressed, anxious, guilty, or tense.

INVEGA is also used to treat schizoaffective disorder in adults.

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).

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

2. What you need to know before you take INVEGA

Do not take INVEGA
- if you are allergic to paliperidone, risperidone, or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking INVEGA.

- Patients with schizoaffective disorder treated with this medicine should be carefully monitored for a potential switch from manic to depressive symptoms.
- This medicine 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. (see section 4, possible side effects).
- 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). You should be aware that both of these conditions may be caused by this type of medicine.
- if you know that you have had low levels of white blood cells in the past (which may or may not have been caused by other medicines).
- if you are diabetic or prone to diabetes.
- if you have heart disease or heart disease treatment that makes you prone to low blood pressure.
- if you have epilepsy.
- if you have a swallowing, stomach or intestinal disorder that reduces your ability to swallow or pass foods by normal bowel movements.
- if you have diseases associated with diarrhoea.
- if you have kidney problems.
- if you have liver problems.
- if you have prolonged and/or painful erection.
- if you have difficulty controlling core body temperature or overheating.
- if you have an abnormally high level of the hormone prolactin in your blood or if you have a possible prolactin-dependent tumour.
- if you or someone else in your family has a history of blood clots, as antipsychotics have been associated with formation of blood clots.

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

As dangerously low numbers of a certain type of white blood cell needed to fight infection in your blood has been seen very rarely with patients taking INVEGA, your doctor may check your white blood cell counts.

INVEGA may cause you to gain weight. Significant weight gain may adversely affect your health. Your doctor should regularly measure your body weight.

As diabetes mellitus or worsening of pre-existing diabetes mellitus have been seen with patients taking INVEGA, your doctor should check for signs of high blood sugar. In patients with pre-existing diabetes mellitus blood glucose should be monitored regularly.

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 coloured 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.

Children and adolescents
INVEGA is not for use in children and adolescents under 15 years for the treatment of schizophrenia.

INVEGA is not for use in children and adolescents who are under 18 years for the treatment of schizoaffective disorder.

This is because it is not known if INVEGA is safe or effective in these age groups.

Other medicines and INVEGA
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

Abnormalities of electrical function in the heart may occur when this medicine is taken with certain heart medicines that control heart rhythm, or some other types of medicines such as antihistamines, antimalarials, or other antipsychotics.

Since this medicine works primarily in the brain, interference from other medicines (or alcohol) that work in the brain could occur due to additive effect on brain function.

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

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

The effects of this medicine may be affected if you are taking medicines that affect the speed of movement in the gut (e.g., metoclopramide).

Dosage reduction for this medicine should be considered when this medicine is co-administered with valproate.

The use of oral risperidone together with this medicine is not recommended as the combination of the two medicines may lead to increased side effects.

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

INVEGA with alcohol
Alcohol should be avoided when taking this medicine.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. You should not take this medicine during pregnancy unless this has been discussed with your doctor. The following symptoms may occur in newborn babies of mothers that have used paliperidone in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.
You should not breastfeed when taking this medicine.

Driving and using machines
Dizziness and vision problems may occur during treatment with this medicine (see section 4, possible side effects). This should be considered in cases where full alertness is required, e.g., when driving a car or handling machines.

The 3 mg tablet of INVEGA contains lactose
The 3 mg tablet of this medicine contains lactose, a type of sugar. If you have been told by a doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

INVEGA contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take INVEGA

Take this medicine exactly as the doctor, pharmacist or nurse has told you to.

Use in adults
The recommended dose in adults is 6 mg once a day taken in the morning. The dose may be increased or decreased by your doctor within the dose range of 3 mg to 12 mg once a day for schizophrenia or 6 mg to 12 mg once a day for schizoaffective disorder. This depends on how well the medicine works for you.

Use in adolescents
The recommended starting dose for treating schizophrenia in adolescents 15 years and older is 3 mg once a day taken in the morning.

For adolescents weighing 51 kg or more the dose may be increased within the range of 6 mg to 12 mg once a day.

For adolescents weighing less than 51 kg the dose may be increased to 6 mg once a day.

Your doctor will decide how much to give you. The amount you take depends on how well the medicine works for you.

How and when to take INVEGA
This medicine must be taken by mouth, swallowed whole with water or other liquids. It must not be chewed, broken, or crushed.

This medicine should be taken every morning with breakfast or without breakfast, but in the same way every day. Do not alternate between taking this medicine with breakfast one day and without having breakfast the next day.

The active ingredient, paliperidone, dissolves once swallowed and the tablet shell is passed out of the body as waste.

Patients with kidney problems
Your doctor may adjust your dose of this medicine based upon your kidney function.

Elderly
Your doctor may reduce your dose of medicine if your kidney function is reduced.

If you take more INVEGA than you should
Contact your doctor right away. You may experience sleepiness, tiredness, abnormal body movements, problems with standing and walking, dizziness from low blood pressure, and abnormal heart beats.

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
Do not stop taking this medicine since 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 medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

Tell your doctor immediately if you:

- experience blood clots in the veins, especially in the legs (symptoms include swelling, pain, and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty breathing. If you notice any of these symptoms seek medical advice immediately.
- have dementia and experience a sudden change in your mental state or sudden weakness or numbness of your face, arms or legs, especially on one side, or slurred speech, even for a short period of time. These may be signs of a stroke.
- experience fever, muscle stiffness, sweating or a lowered level of consciousness (a disorder called “Neuroleptic Malignant Syndrome”). Immediate medical treatment may be needed.
- are a man and experience prolonged or painful erection. This is called priapism. Immediate medical treatment may be needed.
- experience involuntary rhythmic movements of the tongue, mouth and face. Withdrawal of paliperidone may be needed.
- experience a severe allergic reaction characterised 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’).

Very common: may affect more than 1 in 10 people

- difficulty falling or staying asleep
- 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 signs 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.
- restlessness
- feeling sleepy or less alert
- headache.

Common side effects: may affect up to 1 in 10 people

- infection of the chest (bronchitis), common cold symptoms, sinus infection, urinary tract infection, feeling like you have the flu
- weight gain, increased appetite, weight loss, decreased appetite
- elated mood (mania), irritability, depression, anxiety
- 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.
- dizziness
- dyskinesia: This is a condition involving involuntary muscle movements, and can include repetitive, spastic or writhing movements, or twitching.
- tremor (shaking)
- blurry vision
- 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, slow heart rate, 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
- sore throat, cough, stuffy nose
- abdominal pain, abdominal discomfort, vomiting, nausea, constipation, diarrhoea, indigestion, dry mouth, toothache
- increased liver transaminases in your blood
- itching, rash
- bone or muscle ache, back pain, joint pain
- loss of menstrual periods
- fever, weakness, fatigue (tiredness).

Uncommon side effects: may affect up to 1 in 100 people

- pneumonia, infection of the breathing passages, bladder infection, ear infection, tonsillitis
- white blood cell count decreased, decrease in platelets (blood cells that help you stop bleeding), anaemia, decrease in red blood cells
- INVEGA 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.
- diabetes or worsening diabetes, high blood sugar, increased waist size, loss of appetite resulting in malnutrition and low body weight, high blood triglycerides (a fat)
- sleep disorder, confusion, decreased sexual drive, inability to reach orgasm, nervousness, 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 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
- oversensitivity of the eyes to light, eye infection or "pink eye", dry eye
- a sensation of spinning (vertigo), ringing in the ears, ear pain
- irregular heartbeat, 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, nosebleeds
- swollen tongue, stomach or intestinal infection, difficulty swallowing, 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”), hair loss, eczema, acne
- an increase of CPK (creatine phosphokinase) in your blood, an enzyme which is sometimes released with muscle breakdown, muscle spasms, joint stiffness, joint swelling, muscle weakness, neck pain
- incontinence (lack of control) of urine, frequent passing of urine, inability to pass urine, pain when passing urine
- erectile dysfunction, ejaculation disorder
- missed menstrual periods or other problems with your cycle (females), leakage of milk from the breasts, sexual dysfunction, breast pain, breast discomfort
- swelling of the face, mouth, eyes, or lips, swelling of the body, arms or legs
- chills, an increase in body temperature
- a change in the way you walk
- feeling thirsty
- chest pain, chest discomfort, feeling unwell
- fall.

Rare side effects: may affect up to 1 in 1,000 people

- eye infection, fungal infection of the nails, infection of the skin, skin inflammation caused by mites
- dangerously low numbers of a certain type of white blood cell needed to fight infection in your blood
- decrease in the type of white blood cells that help to protect you against infection, increase in eosinophils (a type of white blood cell) in your blood
- severe allergic reaction characterised by fever, swollen mouth, face, lip or tongue, shortness of breath, itching, skin rash and sometimes drop in blood pressure, allergic reaction
- sugar in the urine

- inappropriate secretion of a hormone that controls urine volume
- life threatening complications of uncontrolled diabetes
- dangerously excessive intake of water, low blood sugar, excessive drinking of water, increased cholesterol in your blood
- sleep walking
- not moving or responding while awake (catatonia)
- lack of emotion
- neuroleptic malignant syndrome (confusion, reduced or loss of consciousness, high fever, and severe muscle stiffness)
- loss of consciousness, balance disorder, abnormal coordination
- blood vessel problems in the brain, coma due to uncontrolled diabetes, unresponsive to stimuli, low level of consciousness, shaking of the head
- glaucoma (increased pressure within the eyeball), increased tears, redness of the eyes, problems with movement of your eyes, eye rolling
- atrial fibrillation (an abnormal heart rhythm), rapid heartbeat upon standing
- blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing. If you notice any of these symptoms seek medical advice immediately
- decreased oxygen in parts of your body (because of decreased blood flow), flushing
- trouble breathing during sleep (sleep apnea), fast, shallow breathing
- pneumonia caused by inhaling food, congestion of breathing passages, voice disorder
- a blockage in the bowels, stool incontinence, very hard stool, lack of bowel muscle movement that causes blockage
- yellowing of the skin and the eyes (jaundice)
- inflammation of the pancreas
- serious allergic reaction with swelling that may involve the throat and lead to difficulty breathing
- thickening of the skin, dry skin, skin redness, skin discolouration, flaky itchy scalp or skin, dandruff
- breakdown of muscle fibers and pain in muscles (rhabdomyolysis), abnormal posture
- priapism (a prolonged penile erection that may require surgical treatment)
- development of breasts in men, enlargement of the glands in your breasts, discharge from the breasts, vaginal discharge
- a delay in menstrual periods, breast enlargement
- very low body temperature, a decrease in body temperature
- symptoms of drug withdrawal.

Not known: frequency cannot be estimated from the available data
- lung congestion
- increased insulin (a hormone that controls blood sugar levels) in your blood.

The following side effects have been seen with the use of another medicine called risperidone that is very similar to paliperidone, so these can also be expected with INVEGA: sleep-related eating disorder, other types of blood vessel problems in the brain, crackly lung sounds, and 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/toxic epidermal necrolysis). Eye problems during cataract surgery may also occur. 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 this medicine.

Additional side effects in adolescents
Adolescents generally experienced side effects that were similar to those seen in adults except the following side effects were seen more commonly:
- feeling sleepy or less alert

- 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 signs 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.
- weight gain
- common cold symptoms
- restlessness
- tremor (shaking)
- stomach pain
- leaking milk from the breasts in girls
- breast swelling in boys
- acne
- problems with speech
- stomach or intestinal infection
- nose bleeds
- ear infection
- high blood triglycerides (a fat)
- sensation of spinning (vertigo).

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
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By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store INVEGA

Keep this medicine out of the sight and reach of children.

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

Blisters: Do not store above 30°C. Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What INVEGA contains
The active substance is paliperidone
Each INVEGA 3 mg prolonged-release tablet contains 3 mg of paliperidone.
Each INVEGA 6 mg prolonged-release tablet contains 6 mg of paliperidone.
Each INVEGA 9 mg prolonged-release tablet contains 9 mg of paliperidone.

The other ingredients are:
Coated tablet core:
Polyethylene oxide 200K
Sodium chloride
Povidone (K29-32)
Stearic acid
Butyl hydroxytoluene (E321)

Ferric Oxide (Yellow) (E172) (3 tablet only)
Polyethylene Oxide 7000K
Ferric Oxide (Red) (E172)
Hydroxyethyl Cellulose
Polyethylene glycol 3350
Cellulose acetate
Iron oxide (Black) (E172) (9 mg tablet only)

Colour overcoat:
Hypromellose
Titanium dioxide (E171)
Polyethylene glycol 400 (6 and 9 tablet only)
Ferric Oxide (Yellow) (E172) (6 tablet only)
Ferric Oxide (Red) (E172) (6, 9 mg tablet only)
Lactose monohydrate (3 mg tablet only)
Triacetin (3 mg tablet only)
Carnauba wax

Printing ink:
Iron oxide (Black) (E172)
Propylene glycol
Hypromellose

What INVEGA looks like and contents of the pack
INVEGA prolonged-release tablets are capsule shaped. The 3 mg tablets are white and printed with "PAL 3", the 6 mg tablets are beige and printed with "PAL 6", and the 9 mg tablets are pink and printed with "PAL 9". All tablets are available in the following pack sizes:

- Blisters: The tablets are supplied in blisters packed in cartons of, 28 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Janssen-Cilag Limited
50-100 Holmers Farm Way
High Wycombe
Buckinghamshire
HP12 4EG
UK

Manufacturer
Janssen-Cilag SpA
Via C. Janssen
04100 Borgo San Michele
Latina
Italy

For information in large print, tape, CD or Braille, telephone 0800 7318450

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