Package leaflet: Information for the user

INVEGA® 3 mg prolonged-release tablets INVEGA® 6 mg prolonged-release tablets INVEGA® 9 mg prolonged-release tablets INVEGA® 12 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 What INVEGA is and what it is used for
 What you need to know before you take INVEGA
 How to take INVEGA

- Possible side effects How to store INVEGA
 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such as hearing things, seeing or sensing things that are not there, mistaken beliefs, unusual suspiciousness, becoming withdrawn, incoherent speech, and behaviour and emotional flatness.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 Schizoattective 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).

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).

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

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).

- increased risk of stroke or ueaus, tose section, purished 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 modicine. 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 adolescentsINVEGA 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.

metoclopramide).

Other medicines and INVEGA

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.

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

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.,

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 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 machinesDizziness 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 contains less than 1 mmol sodium (23 mg) per

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

tablet, that is to say essentially 'sodium-free'

INVEGA contains sodium

3. How to take INVEGA

this medicine

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.

function is reduced.

If you forget to take INVEGA

ask your doctor, pharmacist or nurse

Tell your doctor immediately if you:

heart beats

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.

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

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

If you have any further questions on the use of this medicine,

experience blood clots in the veins, especially in the leas

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.

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

(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 (moking your more people).
- (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
- 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

- 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
- neart, prolongation of the QT interval from your neart, 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
- 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.
- (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 waist size, loss of appetite resulting in malnutrition and low body weight, high blood triglycerides (a fat) sleep disorder, confusion, decreased sexual drive, inability

- (electrocardiogram or ECG), a fluttering or pounding feeling in your chest (palpitations)
- low blood pressure shortness of breath, wheezing, nosebleeds swellen 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
- in your blood
- breakdown, muscle spasms, joint stiffness, joint swelling, muscle weakness, neck pain incontinence (lack of control) of urine, frequent passing of
- 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

- rash and sometimes drop in blood pressure, allergic reaction
- life threatening complications of uncontrolled diabetes dangerously excessive intake of water, low blood sugar, excessive drinking of water, increased cholesterol in your
- sleep walking not moving or responding while awake (catatonia)
- eyes, eye rolling atrial fibrillation (an abnormal heart rhythm), rapid heartbeat
- 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
- 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 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 and crackly lung sounds. 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.

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 less of oversesion on the face. loss of expression on the face. weight gain common cold symptoms restlessness tremor (shaking) stomach pain

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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store INVEGA

high blood triglycerides (a fat) sensation of spinning (vertigo).

ear infection

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.

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

Printing ink: Iron oxide (Black) (E172) Propylene glycol Hypromellos What INVEGA looks like and contents of the pack

Carnauba wax

Not all pack sizes may be marketed.

B-2340 Beerse Janssen Cilag Manufacturing LLC, State Road 933-Km 0.1 Mamey Ward, Gurabo,Puerto Rico 00778.

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

dry eye a sensation of spinning (vertigo), ringing in the ears, ear pain irregular heartbeat, abnormal electrical tracing of the heart

- 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
- incontinence (lack of control) of urine, frequent passing or 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 leas
- 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
- 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, balance disorder, and the head statement of the shaking of the head glaucoma (increased pressure within the eyeball), increased tears, redness of the eyes, problems with movement of your
- breathing pneumonia caused by inhaling food, congestion of breathing passages, voice disorder 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
- 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 composite the following side effects were seen more composite the following side effects.
- leaking milk from the breasts in girls breast swelling in boys acne problems with speech stomach or intestinal infection nose bleeds
- Bottles: Do not store above 30°C. Keep the bottle tightly closed in order to protect from moisture.

Each INVEGA 9 mg prolonged-release tablet contains 9 mg of paliperidone. Each INVEGA 12 mg prolonged-release tablet contains 12 mg

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.

Polyethylene glycol 400 (6, 9 and 12 mg tablet only)
Ferric Oxide (Yellow) (E172) (6, 12 mg tablet only)
Ferric Oxide (Red) (E172) (6, 9 mg tablet only)
Lactose monohydrate (3 mg tablet only)
Triacetin (3 mg tablet only)

pouches which are provided to absorb moisture and keep the tablets dry. Blisters: The tablets are supplied in blisters packed in cartons of 7, 14, 28, 30, 49, 56, and 98 tablets.

This leaflet was last revised in 13 September 2018

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 Povidone (K29-32) Foviorie (K29-32) Stearic acid Butyl hydroxytoluene (E321) Ferric Oxide (Yellow) (E172) (3, 12 mg tablet only) Polyethylene Oxide 7000K Ferric Oxide (Red) (E172) Hydroxyethyl Cellulose Polyethylene glycol 3350 Cellulose acetate Iron oxide (Black) (E172) (9 mg tablet only) 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 Colour overcoat: Hypromellose Titanium dioxide (E171)

> in the following pack sizes: Bottles: The tablets are supplied in a plastic bottle with a child-resistant plastic cap. Each bottle contains either 30 tablets or 350 tablets. Each bottle contains two silica gel

Medicament is a product which affects your neatm and its consumption contrary to instructions is dangerous for you. Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament. The doctor and the pharmacist are the experts in medicines, their benefits and risks.

Do not by yourself interrupt the period of treatment prescribed.

prescribed.

Do not repeat the same prescription without consulting

Keep all medicaments out of the reach of children

Council of Arab Health Ministers, Union of Arab Pharmacists

paliperidone.
Each INVEGA 6 mg prolonged-release tablet contains 6 mg of The other ingredients are: Coated tablet core Polyethylene oxide 200K Sodium chloride

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", the 9 mg tablets are pink and printed with "PAL 9", and the 12 mg tablets are dark yellow and printed with "PAL 12". All tablets are available

Marketing Authorisation Holder Janssen-Cilag International NV Turnhoutseweg 30

Medicament is a product which affects your health and its