

INVEGA[®] prolonged release tablets

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using INVEGA?

INVEGA contains the active ingredient paliperidone. INVEGA is used to treat adults with symptoms of schizophrenia, a mental illness with disturbances in thinking, feelings and behaviour. It is also used to treat other types of related psychoses.

For more information, see Section [1. Why am I using INVEGA?](#) in the full CMI.

2. What should I know before I use INVEGA?

Do not use if you have ever had an allergic reaction to paliperidone, medicines containing risperidone (e.g. RISPERDAL), or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use INVEGA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with INVEGA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use INVEGA?

- Your doctor will decide the dose of INVEGA that is suitable for you, based on your condition and kidney function.
- INVEGA should be used once daily, in the morning, at about the same time each day.
- The tablet should be swallowed whole with water or other liquid. INVEGA tablets must not be chewed, split or crushed.

More instructions can be found in Section [4. How do I use INVEGA?](#) in the full CMI.

5. What should I know while using INVEGA?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using INVEGA. • If you are planning to have operation on your eye, make sure you tell your eye doctor that you are taking this medicine.
Things you should not do	• Do not stop using this medicine suddenly or change your dose without checking with your doctor. • Avoid excessive eating.
Driving or using machines	• Avoid driving or operating machinery until you are sure that INVEGA does not affect your alertness.
Drinking alcohol	• Do not drink alcohol while using INVEGA.
Looking after your medicine	• Keep the tablets in a dry place where the temperature stays below 25°C. • Store it in a cool dry place away from moisture, heat or sunlight.

For more information, see Section [5. What should I know while using INVEGA?](#) in the full CMI.

6. Are there any side effects?

The very common side effects include difficulty falling or staying asleep and headache. Tell your doctor immediately, or go to Emergency at your nearest hospital if you notice any of the following signs: serious allergic reactions, heart or blood pressure problems, high blood sugar or diabetes, severe or life-threatening rash with blisters and peeling skin, sudden weakness or numbness of the face, arms, or legs, especially on one side, or instances of slurred speech (mini-strokes), involuntary movements of the tongue, mouth, cheeks or jaw which may progress to the arms and legs (tardive dyskinesia), fever, muscle stiffness, sweating or a lowered level of consciousness (symptoms of neuroleptic malignant syndrome).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

INVEGA® prolonged release tablets

Active ingredient(s): *paliperidone*

Consumer Medicine Information (CMI)

This leaflet provides important information about using INVEGA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using INVEGA.**

Where to find information in this leaflet:

1. [Why am I using INVEGA?](#)
2. [What should I know before I use INVEGA?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use INVEGA?](#)
5. [What should I know while using INVEGA?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using INVEGA?

INVEGA contains the active ingredient paliperidone.

INVEGA belongs to a group of medicines called antipsychotic agents which improve the symptoms of certain types of mental illness.

INVEGA is used to treat symptoms of schizophrenia, a mental illness with disturbances in thinking, feelings and behaviour. It is also used to treat other types of related psychoses. INVEGA helps to correct a chemical imbalance in the brain associated with these conditions.

Your doctor, however, may prescribe this medicine for another use.

INVEGA is not addictive.

2. What should I know before I use INVEGA?

Warnings

Do not use INVEGA if:

- you are allergic to paliperidone, medicines containing risperidone (e.g. RISPERDAL), or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions
 - o Neuroleptic Malignant Syndrome (a serious reaction to some medicines that causes a sudden increase in body temperature, very fast heartbeat, extremely high or low blood pressure and severe muscle stiffness or fits)
 - o Tardive dyskinesia (a reaction to some medicines with involuntary movements of the tongue, face, mouth, jaws, arms, legs or trunk)
 - o irregular heart rhythm, high or low blood pressure or you've had a heart attack or stroke in the past

- o you are prone to dizziness when standing up from a lying or sitting position
- o unusual, excessive sweating or diarrhoea, dehydration or problems with your body temperature regulation
- o epilepsy, fits, seizures
- o involuntary movements or unusual restlessness or difficulty sitting still
- o Parkinson's Disease (a progressive movement and thinking disorder that tends to affect older people)
- o suicidal thoughts or past suicide attempts
- o inflammation of the lungs due to aspiration (the inhalation of food particles or fluids into the lungs).
- o any problems with swallowing, or stomach or intestinal disorders that reduces your ability to keep food down and/or pass normal bowel movements
- o kidney or liver problems
- o any problems with confusion or unsteadiness
- o dementia or Lewy body dementia: Older people suffering dementia may be at an increased risk of stroke or death with INVEGA.
- o sugar diabetes
- o unusual thirst, tiredness, blurred vision, upset stomach or need to urinate - common signs of high blood sugars
- o stroke or other brain blood vessel problems
- o continuous and/or painful erection (called 'priapism')
- o low white blood cell count: If you have low numbers of some white blood cells, your risk of contracting an infection or developing a fever is increased with INVEGA.
- o blood clots: Tell your doctor if you or someone else in your family has a history of blood clots. Blood clots in the lungs and legs can occur with INVEGA. Blood clots in the lungs can result in death.

- take any medicines for any other condition
- have any eye surgery planned. Your doctor will need to assess whether you are at increased risk of a surgical complication (called 'Intraoperative Floppy Iris Syndrome'. You may be recommended to stop INVEGA temporarily leading up to your eye surgery.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Your doctor will advise you whether or not you should take INVEGA. Newborn babies of mothers taking INVEGA in their last trimester may be at risk of

having difficulty feeding or breathing, shaking, muscle stiffness and/or weakness, sleepiness or agitation.

Talk to your doctor if you are breastfeeding or intend to breastfeed. As INVEGA is excreted in breast milk, it is recommended that you do not breast-feed while you use INVEGA.

Elderly Patients

- Your doctor may adjust your dose based on your kidney function.

Children and Adolescents

- INVEGA is not recommended for treating people who are younger than 18 years old.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with INVEGA and affect how it works.

In particular, tell your doctor if you are taking:

- sleeping tablets, tranquillisers, painkillers, or some allergy medications called antihistamines
- medicines to treat epilepsy
- medicines to treat depression, panic disorder, anxiety or obsessive-compulsive disorder
- medicines that increase the activity of the central nervous system (psychostimulants such as methylphenidate)
- any medicines to treat irregular heart rhythms or heart failure
- any medicines to treat high blood pressure, including water tablets (diuretics)
- other medicines to treat mental illnesses or psychotic conditions
- medicines to relieve nausea or vomiting, indigestion, reflux or other stomach problems
- some medicines to treat malaria.

Your doctor will need to consider whether any of the above medicines will affect your INVEGA.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect INVEGA.

4. How do I use INVEGA?

How much to use

- Your doctor will decide the strength and dose of INVEGA that is suitable for you, based on your condition and kidney function.
- The usual dosage for INVEGA is between 3 mg and 12 mg once daily.
- For people with severe kidney problems the starting dose may be as low as 3 mg every other day. Your

doctor may later decide to increase the dose as required for best symptoms control.

- Follow the instructions provided and use INVEGA until your doctor tells you to stop.

When to use INVEGA

- INVEGA should be used once daily, in the morning, at about the same time each day.
- You should decide whether you will always take INVEGA on an empty stomach before breakfast, or always with food at breakfast. You must not switch between taking INVEGA on an empty stomach and taking it with food.

How to use INVEGA

- The tablet should be swallowed whole with water or other liquid. INVEGA tablets must not be chewed, split or crushed.
- INVEGA tablets are formulated with a special shell that controls the release of the active ingredient gradually throughout the day. The tablet shell does not dissolve completely after all the drug has been released and sometimes the tablet shell may be seen in your stool. This is normal.

If you forget to use INVEGA

INVEGA should be used regularly at the same time each day. If you miss your dose at the usual time, take the missed dose as soon as you remember. Then resume taking INVEGA as you normally would the following morning.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

- If you forget to take it for a number of days or more, tell your doctor before starting your medicine again.
- If you have problems remembering when to take your medicine, ask your pharmacist for some hints.

If you use too much INVEGA

If you think that you have used too much INVEGA, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

Signs of overdose may include drowsiness, dizziness, sleepiness, excessive trembling, nausea, excessive muscle stiffness, increased heart rate, shortness of breath, very low blood pressure causing fainting or unconsciousness.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using INVEGA?

Things you should do

Follow your doctor's instructions carefully.

Always seek your doctor's advice before changing or stopping treatment. Your doctor will be happy to discuss any questions you may have with your treatment.

Ask your doctor or pharmacist before taking any other medicines.

INVEGA can increase the effects of medicines which slow down your reactions. Always ask your doctor or pharmacist before taking other medicines including herbal treatments and medicines that can be bought in a pharmacy or supermarket.

Call your doctor straight away if you:

- are pregnant or planning to become pregnant.
- **notice any involuntary movements of the tongue, mouth, cheeks or jaw.**

These may be symptoms of a condition called tardive dyskinesia, which can develop in people taking antipsychotic medicines, including INVEGA. This condition is more likely to occur during longer term treatment and in older women. In very rare cases, these symptoms may be permanent. However, if detected early, these symptoms are usually reversible.

Remind any doctor, dentist or pharmacist you visit that you are using INVEGA.

Your doctor, dentist or pharmacist will need to consider whether any new medicines will affect your INVEGA.

Things you should not do

- Do not stop using this medicine suddenly or change your dose without first checking with your doctor.
- Do not take it to treat any other complaints unless your doctor says it is safe to do so.
- Do not give this medicine to anyone else, even if their symptoms seem similar.
- Avoid excessive eating.

There is a possibility of weight gain when taking INVEGA. Your doctor may monitor your body weight or recommend strategies to assist with weight management.

Taking it for the first time

- At the start of treatment, you may have a fall in blood pressure making you feel dizzy on standing up, or your heart may beat faster. These should go away after a few days. Tell your doctor if these symptoms continue or worry you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how INVEGA affects you.

INVEGA may cause dizziness, drowsiness or light-headedness in some people, especially after the first dose.

Make sure you know how you react to INVEGA before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol can increase the effects of alcohol. You should not drink alcohol while taking INVEGA.

Looking after your medicine

- Keep the tablets in a dry place where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

Medicines cannot be stored indefinitely, even if stored properly.

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Medicines should not be disposed of via wastewater or household waste.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Difficulty thinking, working or carrying out your usual daily activities because of: • nausea • headache • trembling, muscle weaknesses, unsteadiness on your feet or lack of coordination • sleeplessness, drowsiness, tiredness, lack of energy or difficulty in concentrating Behavioural changes such as: • irritability or agitation	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
- unusual anxiety or depression - unusually elated mood (mania) - lack of emotion Joint/Movement changes such as: - muscle tightness or stiffness, writhing movements, spasm or muscle pain - unusual restlessness, repetitive or involuntary movements - unusual facial movements or a sustained upwards stare Signs and symptoms of problems in other organs: - unexplained increase in appetite or weight gain - diarrhoea, indigestion, heartburn, abdominal pain, constipation - common cold or "flu-like" symptoms such as coughing or stuffy nose - inability to or pain when passing urine - dry mouth, distorted taste sensation, unexplained salivation or drooling - acne - dry skin - reddening or discolouration of skin - nosebleeds - unusual thirst, tiredness, upset stomach or need to urinate - unusual secretion of breast milk, breast swelling, missed or irregular menstrual periods - decreased sexual drive - difficulty getting or maintaining an erection; or having continuous and/or painful erection	

Serious side effects

Serious side effects	What to do
Signs of serious allergic reactions that may include: - rash, itching or hives on the skin - shortness of breath, wheezing or difficulty breathing - swelling of the face, lips, tongue or other parts of the body Signs of heart or blood pressure problems such as: - fainting, blurry vision, light-headedness or dizziness,	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects	What to do
particularly on standing, that persists despite sitting or lying down - very fast heart rate or heart rhythm irregularities Signs of high blood sugar or diabetes such as: - unusual thirst - tiredness - upset stomach - need to urinate more often than usual Signs of skin problems: - 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) Signs of problems in nervous system: - sudden weakness or numbness of the face, arms, or legs, especially on one side, or instances of slurred speech (these are called mini-strokes) - involuntary movements of the tongue, face, mouth, cheeks, jaw, arms, legs or trunk (symptoms of tardive dyskinesia) - unexplained high body temperature, excessive sweating, severe muscle stiffness, confusion, or a lowered level of consciousness (symptoms of neuroleptic malignant syndrome)	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What INVEGA contains

Active ingredient (main ingredient)	paliperidone
Other ingredients (inactive ingredients)	butylated hydroxytoluene carnauba wax cellulose acetate hyetellose hypromellose iron oxide black iron oxide red iron oxide yellow - 3 & 6 mg only lactose monohydrate - 3 mg only macrogol 3350 macrogol 400 - 6 & 9 mg only polyethylene oxide povidone sodium chloride stearic acid titanium dioxide triacetin - 3 mg only
Potential allergens	lactose monohydrate - 3 mg only

Do not take this medicine if you are allergic to any of these ingredients.

What INVEGA looks like

You can identify INVEGA tablets by their colour and shape. This is important because each type of tablets, contains a different amount of the active paliperidone:

- 3 mg prolonged release tablet blister pack (Aust R 130502): White, capsule shaped tablets imprinted with "PAL 3"
- 6 mg prolonged release tablet blister pack (Aust R 130714): Beige, capsule shaped tablets imprinted with "PAL 6"
- 9 mg prolonged release tablet blister pack (Aust R 130717): Pink, capsule shaped tablets imprinted with "PAL 9"

Do not take it if the tablets appearance has changed.

All tablets come in blister packs of 28 tablets.

Not all strengths may be marketed.

Who distributes INVEGA

Janssen-Cilag Pty Ltd

1-5 Khartoum Road

Macquarie Park NSW 2113

Telephone: 1800 226 334

NZ Office: Auckland New Zealand

Telephone: 0800 800 806

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