

INVEGA TRINZA[®]

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 TRINZA?

INVEGA TRINZA contains the active ingredient paliperidone palmitate. INVEGA TRINZA is used to treat schizophrenia in adults (18 years of age and older).

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

2. What should I know before I use INVEGA TRINZA?

Do not use if you have ever had an allergic reaction to medicines containing paliperidone (e.g. INVEGA) or 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 TRINZA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with INVEGA TRINZA 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 TRINZA?

- Treatment with INVEGA TRINZA should not be started by your doctor until they know you have tolerated INVEGA SUSTENNA for at least 4 months. After you have been given the first dose, it is recommended that INVEGA TRINZA is given once every 3 months.
- INVEGA TRINZA is administered by your doctor or other healthcare professional in a doctor's office or clinic. Your doctor or other healthcare professional will give you the injection into the muscle of your upper arm or buttocks.
- Your doctor will decide the strength of INVEGA TRINZA that is suitable for you.

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

5. What should I know while using INVEGA TRINZA?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using paliperidone.• 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	<ul style="list-style-type: none">• Do not miss any injections or any appointments with the doctor.
Driving or using machines	<ul style="list-style-type: none">• Make sure you know how you react to INVEGA TRINZA before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy.
Drinking alcohol	<ul style="list-style-type: none">• Avoid drinking alcohol while using INVEGA TRINZA.

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

6. Are there any side effects?

The very common side effects include difficulty falling or staying asleep. 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 (Stevens-Johnson syndrome or toxic epidermal necrolysis), 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 TRINZA[®]

Active ingredient(s): *paliperidone palmitate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using INVEGA TRINZA. **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 TRINZA.**

Where to find information in this leaflet:

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

1. Why am I using INVEGA TRINZA?

INVEGA TRINZA contains the active ingredient **paliperidone palmitate**. INVEGA TRINZA belongs to a group of medicines called antipsychotic agents which improve the symptoms of certain types of mental illness.

INVEGA TRINZA is used to treat adults with symptoms of schizophrenia, a mental illness with disturbances in thinking, feelings and behaviour.

INVEGA TRINZA helps to correct a chemical imbalance in the brain associated with this condition. It can also be used to lessen the chance of your schizophrenia symptoms from coming back.

Some of the most common symptoms of schizophrenia may include:

- Seeing, hearing, or sensing things that are not there (hallucinations)
- A false belief or wrong judgment, sometimes associated with hallucinations, held with conviction despite evidence to the contrary (delusions)
- Not trusting others and feeling very suspicious (paranoia)
- Avoiding family and friends and wanting to be alone

It may take some time before your symptoms of schizophrenia start to improve. Remember that INVEGA TRINZA is one part of your overall treatment plan. It is important to keep all your appointments, so you can get your treatments on time and your doctor can check your progress.

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

2. What should I know before I use INVEGA TRINZA?

Warnings

Do not use INVEGA TRINZA if:

- you are allergic to paliperidone (e.g. INVEGA) or 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.

Signs of allergy may include skin rash, itching, shortness of breath, and/or swollen face or tongue.

Check with your doctor if you:

- have any other medical conditions
 - 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)
 - Tardive dyskinesia (a reaction to some medicines with involuntary movements of the tongue, face, mouth, jaws, arms, legs or trunk)
 - irregular heart rhythm, low or high blood pressure or you've had a heart attack or stroke in the past
 - you are prone to dizziness when standing up from a lying or sitting position
 - unusual, excessive sweating or diarrhoea, dehydration or problems with your body temperature regulation
 - epilepsy, fits, seizures, involuntary movements or unusual restlessness
 - suicidal thoughts or past suicide attempts
 - inflammation of the lungs due to aspiration (the inhalation of food particles or fluids into the lungs).
 - any problems with swallowing, or stomach or intestinal disorders that reduces your ability to keep food down and/or pass normal bowel movements
 - kidney or liver problems
 - dementia or Lewy body dementia
Older people suffering dementia may be at an increased risk of stroke or death with INVEGA TRINZA
 - any problems with confusion or unsteadiness
 - Parkinson's disease (a progressive movement and thinking disorder that tends to affect older people)
 - sugar diabetes
If you already have diabetes, have risk factors

(such as being overweight or a family history of diabetes) or possible signs of diabetes (unusual thirst, tiredness, blurred vision, upset stomach or need to urinate), blood sugar testing should be done at the beginning and during the treatment. The complications of diabetes can be serious and even life-threatening.

- o diseases of the blood vessels of the brain, including stroke
 - o continuous and/or painful erection (called 'priapism')
 - o a history of blood clots (or someone else in your family has a history of blood clots). Blood clots in the lungs and legs can occur when using INVEGA TRINZA. Blood clots in the lungs can result in death.
 - 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 TRINZA
- take any medicines for any other condition
 - have any eye surgery planned.
Your doctor will need to assess whether you are at an increased risk of a surgical complication (called 'Intraoperative Floppy Iris Syndrome'. You may be recommended to stop using INVEGA TRINZA 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 use INVEGA TRINZA. Newborn babies of mothers taking INVEGA TRINZA 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 TRINZA is excreted in breast milk, it is recommended that you do not breast-feed while you use INVEGA TRINZA.

Patients with kidney problems

- INVEGA TRINZA has not been studied in patients whose kidney is not functioning properly. Your doctor will decide the dose suitable for you.
- Use of INVEGA TRINZA is not recommended in patients with moderate or severe kidney problems.

Children and adolescents

- INVEGA TRINZA is not recommended for treating people with schizophrenia 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.

In particular, tell your doctor if you are taking:

- sleeping tablets, tranquillisers, painkillers or allergy medicines called antihistamines
- medicines to treat epilepsy or Parkinson's Disease
- medicines to treat depression, panic disorder, anxiety or obsessive-compulsive disorder.
- 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 that increase the activity of the central nervous system (psychostimulants such as methylphenidate)
- medicines to relieve nausea or vomiting, indigestion, reflux or other stomach problems
- some medicines to treat malaria

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 TRINZA.

4. How do I use INVEGA TRINZA?

How much to use

- Your doctor will decide the strength of INVEGA TRINZA suitable for you.
- For patients with mild kidney problems, the maximum recommended dose is 350 mg.
- Follow the instructions provided and use INVEGA TRINZA until your doctor tells you to stop.

When to use INVEGA TRINZA

- Treatment with INVEGA TRINZA should not be started by your doctor until they know you have tolerated INVEGA SUSTENNA for at least 4 months.
- 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.
- After you have been given the first dose, it is recommended that INVEGA TRINZA is given once every 3 months. However, your doctor may change the dose depending on how your body responds to the medicine.
- INVEGA TRINZA helps control your condition but will not cure it. Therefore, you will need regular injections. Do not miss any injections, even if you feel better.

How to use INVEGA TRINZA

- INVEGA TRINZA will be given by injection into the muscle of your upper arm or buttocks.

- INVEGA TRINZA is administered by your doctor or other healthcare 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 very important to keep all your appointments and get your medicine on time.

If you forget to use INVEGA TRINZA

It is very important to keep all your appointments and get your medicine on time.

If you are going to miss or have missed your dose at the usual time, contact your doctor as soon as you can.

Your doctor will decide what you should do next.

If you use too much INVEGA TRINZA

As INVEGA TRINZA is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

However, if you think that you have used too much INVEGA TRINZA, 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.

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

5. What should I know while using INVEGA TRINZA?

Things you should do

- Follow your doctor's instructions carefully.
- If you are planning to have operation on your eye, make sure you tell your eye doctor that you are taking this medicine.
- Ask your doctor or pharmacist before taking any other medicines.

INVEGA TRINZA 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:

- notice any involuntary movements of the tongue, mouth, cheeks or jaw which may progress to the arms and legs.

These may be symptoms of a condition called tardive dyskinesia, which can develop in people taking antipsychotic medicines, including INVEGA TRINZA. 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 TRINZA.

Things you should not do

- Do not miss an injection or stop the treatment suddenly without consulting your doctor first.
- 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.

Driving or using machines

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

INVEGA TRINZA may cause dizziness, drowsiness or light-headedness in some people. Make sure you know how you react to INVEGA TRINZA before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy.

If the medicine makes you feel light-headed, dizzy or faint, be careful when getting up from a sitting or lying position.

Getting up slowly may help.

Drinking alcohol

Do not drink alcohol.

INVEGA TRINZA can increase the effects of alcohol.

Looking after your medicine

INVEGA TRINZA will be stored by your doctor or pharmacist so it is unlikely that you will store this medicine at home. If you do,

- keep the medicine in a cool dry place, protected from light, where the temperature stays below 25°C.
- do not use it beyond the expiry date (month and year) printed on the pack.

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: <ul style="list-style-type: none"> • headache • trembling, muscle weaknesses, unsteadiness on your feet, lack of coordination or slow, shuffling walk 	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
<ul style="list-style-type: none"> difficulty falling or staying asleep, drowsiness, tiredness, difficulty in concentrating pain at injection site <p>Behavioural changes such as:</p> <ul style="list-style-type: none"> irritability or agitation unusual anxiety or depression lack of emotion unusually elevated mood <p>Joint/Movement changes such as:</p> <ul style="list-style-type: none"> muscle or joint stiffness or pain, bone or muscle ache unusual restlessness, repetitive or involuntary movements unusual facial movements with sustained upwards stare <p>Signs and symptoms of problems in other organs:</p> <ul style="list-style-type: none"> unexplained increase in appetite or weight gain weight loss common cold or "flu-like" symptoms such as coughing or stuffy nose inability to or pain when passing urine eye rolling toothache dry mouth, distorted taste sensation, drooling acne dry skin nosebleeds hardening of the skin vomiting, indigestion, abdominal pain diarrhoea constipation leakage of milk from the breasts breast swelling missed or irregular menstrual periods difficulty getting or maintaining an erection; or having continuous and/or painful erection 	

Serious side effects

Serious side effects	What to do
<p>Signs of serious allergic reactions that may include:</p> <ul style="list-style-type: none"> rash, itching or hives on the skin shortness of breath, wheezing or difficulty breathing 	<p>Call your doctor straight away, or go straight to the Emergency Department at</p>

Serious side effects	What to do
<ul style="list-style-type: none"> swelling of the face, lips, tongue or other parts of the body <p>Signs of heart or blood pressure problems such as:</p> <ul style="list-style-type: none"> fall in blood pressure, blurry vision, light-headedness or dizziness particularly on standing despite sitting or lying down very fast heart rate, slowed heart rate, heart rhythm irregularities <p>Signs of high blood sugar or diabetes such as:</p> <ul style="list-style-type: none"> being thirsty all the time having to urinate or "pass urine" more often than usual feeling weak or hungry <p>Signs of skin problems:</p> <ul style="list-style-type: none"> 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) <p>Signs of problems in nervous system:</p> <ul style="list-style-type: none"> 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, 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) 	<p>your nearest hospital if you notice any of these serious side effects.</p>

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 TRINZA contains

Active ingredient (main ingredient)	paliperidone (as palmitate)
Other ingredients (inactive ingredients)	citric acid monohydrate, macrogol 4000, polysorbate 20, monobasic sodium phosphate monohydrate, sodium hydroxide, water for injections.

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

What INVEGA TRINZA looks like

INVEGA TRINZA is available as a white to off-white coloured suspension in pre-filled syringes which contain different amounts of paliperidone (as palmitate) listed below for intramuscular use:

- paliperidone 175 mg equivalent to paliperidone palmitate 273 mg (Aust R 261332)
- paliperidone 263 mg equivalent to paliperidone palmitate 410 mg (Aust R 261406)
- paliperidone 350 mg equivalent to paliperidone palmitate 546 mg (Aust R 261407)
- paliperidone 525 mg equivalent to paliperidone palmitate 819 mg (Aust R 261408)

The pack also contains safety needles

Not all strengths may be marketed.

Who distributes INVEGA TRINZA

Janssen-Cilag Pty Ltd

17 Khartoum Road Macquarie Park NSW 2113

Telephone: 1800 226 334

NZ Office: Auckland New Zealand

Telephone: 0800 800 806

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