

INVEGA SUSTENNA®

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 SUSTENNA?

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

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

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

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 SUSTENNA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with INVEGA SUSTENNA 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 SUSTENNA?

- Treatment with INVEGA SUSTENNA will not be started by your doctor until they know you have already tolerated oral paliperidone or oral / injectable risperidone.
- INVEGA SUSTENNA 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 SUSTENNA which is suitable for you.

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

5. What should I know while using INVEGA SUSTENNA?

Things you should do	• 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	• Do not miss any injections or any appointments with the doctor.
Driving or using machines	• Make sure you know how you react to INVEGA SUSTENNA before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy.
Drinking alcohol	• Avoid drinking alcohol while using INVEGA SUSTENNA.

For more information, see Section [5. What should I know while using INVEGA SUSTENNA?](#) 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 (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 SUSTENNA®

Active ingredient(s): *paliperidone palmitate*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using INVEGA SUSTENNA?

INVEGA SUSTENNA contains the active ingredient paliperidone palmitate. INVEGA SUSTENNA belongs to a group of medicines called antipsychotic agents which improve the symptoms of certain types of mental illness. **INVEGA SUSTENNA** is used to treat adults with symptoms of schizophrenia, a mental illness with disturbances in thinking, feelings and behaviour. INVEGA SUSTENNA 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)
- Believing that what other people say is not true (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 SUSTENNA 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 SUSTENNA?

Warnings

Do not use INVEGA SUSTENNA if:

- you are allergic to paliperidone, or to risperidone which is another antipsychotic medicine similar to paliperidone, 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:
 - 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 abnormal movements of the tongue, face, mouth, jaws, arms, legs or trunk)
 - irregular heart rhythm, high or low blood pressure or you've had a heart attack, stroke or other brain blood vessel problems in the past
 - unusual, excessive sweating or diarrhoea, dehydration or problems with your body temperature regulation
 - epilepsy, convulsion (fits), seizures, or involuntary movements or unusual restlessness
 - dementia or Lewy body dementia. Older people suffering dementia may be at increased risk of stroke or death with INVEGA SUSTENNA
 - Parkinson's disease (a progressive movement and thinking disorder that tends to affect older people)
 - low numbers of some white blood cells as your risk of contracting an infection or developing a fever is increased with INVEGA SUSTENNA
 - at risk for diabetes or high blood sugar (unusual thirst, tiredness, blurred vision, upset stomach or need to urinate - common signs of high blood sugars)
 - heart disease or heart disease treatment that makes you prone to low blood pressure, or are prone to drop in blood pressure or feeling dizzy when you stand up from lying or sitting positions
 - a loss of kidney function. Your doctor may reduce your dose of INVEGA SUSTENNA if your kidney function is reduced
 - a loss of liver function
 - continuous and/or painful erection (called 'priapism')

- a history of blood clots (or someone else in your family has a history of blood clots). Blood clots in the lungs and legs have been seen in patients taking medicines that are similar to INVEGA SUSTENNA. Blood clots in the lungs can result in death
- 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
- any problems with confusion or unsteadiness
- suicidal thoughts or past suicide attempts
- plan to have operation on your eye. 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 SUSTENNA temporarily leading up to your eye surgery.
- take any medicines for any other condition

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 SUSTENNA. Newborn babies of mothers taking INVEGA SUSTENNA 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 SUSTENNA is excreted in breast milk, it is recommended that you do not breast-feed while you use INVEGA SUSTENNA.

Patients with kidney or liver problems

- INVEGA SUSTENNA has not been studied in patients whose kidney is not functioning properly. Your doctor may adjust your dose of INVEGA SUSTENNA based upon your kidney function. Use of INVEGA SUSTENNA is not recommended in patients with moderate or severe kidney function impairment.
- INVEGA SUSTENNA has not been studied in patients with liver impairment, but based on experience with orally-administered paliperidone, adjustment in dose is typically not necessary in patients with mild to moderate liver impairment. The doctor will use his/her best judgement if INVEGA SUSTENNA is being considered for use in a patient with severe liver impairment.

Elderly patients

INVEGA SUSTENNA 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.

Children and adolescents

INVEGA SUSTENNA 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.

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

In particular, tell your doctor if you are taking:

- sleeping tablets, tranquillisers, painkillers or come allergy medications called antihistamines since INVEGA SUSTENNA can make you sleepy or drowsy
- medicines to treat epilepsy or Parkinson's Disease since INVEGA SUSTENNA can reduce the effect of medicines against Parkinson's disease and restless legs syndrome (e.g., levodopa)
- any medicines to treat high blood pressure including water tablets (diuretics) since INVEGA SUSTENNA can lower blood pressure
- any medicines to treat irregular heart rhythms or heart failure
- medicines to treat depression, panic disorder, anxiety or obsessive-compulsive disorder
- 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 SUSTENNA.

4. How do I use INVEGA SUSTENNA?

How much to use

- Your doctor will decide the strength of INVEGA SUSTENNA suitable for you. The usual initial dose of INVEGA SUSTENNA is 150 mg and second dose is 100 mg. The usual monthly dose is 75 mg. However, your doctor might decide to give you a lower or higher dose in the range of 25 mg to 150 mg based on your condition and kidney function.

When to use INVEGA SUSTENNA

- Treatment with INVEGA SUSTENNA will not be started by your doctor until they know you have already tolerated oral paliperidone (e.g. INVEGA) or oral / injectable risperidone (e.g. RISPERDAL).

- It is a medicine designed to gradually release into your body so that you do not have to take this medicine every day. INVEGA SUSTENNA helps control your condition but will not cure it. Therefore, you will need regular injections.
- When you receive your first dose of INVEGA SUSTENNA you will need to get a second dose one week later. Your doctor may choose to give you this second injection four days before or after the second scheduled dose is due. After that you will only need to get a dose once a month. After you have been given the first two doses, it is recommended that INVEGA SUSTENNA is given once every month. However, your doctor may change the dose depending on how your body responds to the medicine.

How to use INVEGA SUSTENNA

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

- Contact your doctor as soon as you can if you think you are going to miss or have missed your appointment. Your doctor will decide what you should do next.

If you use too much INVEGA SUSTENNA

Because INVEGA SUSTENNA is stored and administered by healthcare professionals, the potential for overdose by patients is low.

In overdose, one or more of the following signs may occur: reduced consciousness, drowsiness, sleepiness, excessive trembling, excessive muscle stiffness, fast beating heart, and low blood pressure. Cases of abnormal electrical conduction in the heart (QT prolongation) and convulsion have been reported.

Overdose can happen if you are taking other medications together with INVEGA SUSTENNA.

If you experience the above symptoms, 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 SUSTENNA?

Things you should do

- Follow your doctor's instructions carefully.
- Ask your doctor or pharmacist before taking any other medicines. INVEGA SUSTENNA 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 SUSTENNA. 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.
- develop a fever or infection while being treated with INVEGA SUSTENNA

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

Things you should not do

- Do not miss any injections or any appointments with the doctor.
- Avoid excessive eating. There is a possibility of weight gain when taking INVEGA SUSTENNA. 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 SUSTENNA affects you.

INVEGA SUSTENNA may cause dizziness, drowsiness or light-headedness in some people. Make sure you know how you react to INVEGA SUSTENNA 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 SUSTENNA can increase the effects of alcohol.

Looking after your medicine

INVEGA SUSTENNA 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: - nausea - headache - trembling, muscle weaknesses, unsteadiness on your feet, lack of coordination or slow, shuffling walk - difficulty falling or staying asleep, drowsiness, tiredness, difficulty in concentrating - pain at injection site Behavioural changes such as: - irritability or agitation - unusual anxiety or depression - lack of emotion - unusually elated mood Joint/Movement changes such as: - muscle or joint stiffness or pain, bone or muscle ache - unusual restlessness, repetitive or involuntary movements - unusual facial movements with sustained upwards stare Signs and symptoms of problems in other organs: - unexplained increase in appetite or weight gain - weight loss - eye rolling - common cold or "flu-like" symptoms such as coughing or stuffy nose - toothache - inability to or pain when passing urine - dry mouth, distorted taste sensation, drooling - acne - dry skin - nosebleeds - hardening of the skin	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
- diarrhoea - constipation - vomiting, indigestion, abdominal pain - 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
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: - 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 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	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
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)	

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 SUSTENNA contains

Active ingredient (main ingredient)	paliperidone (as palmitate)
Other ingredients (inactive ingredients)	citric acid monohydrate, macrogol 4000, polysorbate 20, dibasic sodium phosphate, 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 SUSTENNA looks like

INVEGA SUSTENNA 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 25 mg equivalent to paliperidone palmitate 39 mg (Aust R 160858)
- paliperidone 50 mg equivalent to paliperidone palmitate 78 mg (Aust R 160856)
- paliperidone 75 mg equivalent to paliperidone palmitate 117 mg (Aust R 160859)
- paliperidone 100 mg equivalent to paliperidone palmitate 156 mg (Aust R 160860)
- paliperidone 150 mg equivalent to paliperidone palmitate 234 mg (Aust R 160857)

Not all strengths may be marketed.

Who distributes INVEGA SUSTENNA

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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