

INVEGA SUSTENNA®

Modified Release Aqueous Suspension for Intramuscular Injection

Paliperidone palmitate

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some of the common questions about INVEGA SUSTENNA. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

If you have any concerns about using INVEGA SUSTENNA, ask your doctor or pharmacist.

Your doctor and pharmacist have more information.

Keep this information handy.

You can refer to it later if you have any questions.

What INVEGA SUSTENNA is used for

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

It is used to treat 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.

Ask your doctor if you have any questions about why it has been prescribed to you.

Before you take it

When you must not use it

Do not use INVEGA SUSTENNA if you know you are allergic to any of its ingredients listed at the end of this leaflet or medicines containing paliperidone (e.g. Invega) or risperidone (e.g. Risperdal).

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

Do not use it after the expiry date printed on the pack.

If you use it after the expiry date has passed, it may not work as well.

Do not use it if the packaging is torn or shows signs of being tampered with.

Do not use it to treat any other complaints unless your doctor says it is safe to do so.

Before you start to use it

INVEGA SUSTENNA should be used with caution in some people, particularly those who have been diagnosed with more than one medical condition.

1. Before you start using INVEGA SUSTENNA, make sure you tell your doctor if you have or have ever had, the following:

- 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, high or low 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, or 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
 - any problems with confusion or unsteadiness
 - 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)
 - sugar diabetes
 - unusual thirst, tiredness, blurred vision, upset stomach or need to urinate - common signs of high blood sugars
 - stroke or other brain blood vessel problem
 - continuous and/or painful erection (called 'priapism')
 - 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 when using INVEGA SUSTENNA. Blood clots in the lungs can result in death
 - 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 SUSTENNA.
- 2. Tell your doctor if:**
- you have an 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 SUSTENNA temporarily leading up to your eye surgery.

- you are pregnant or are planning 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.

- you are breast feeding.

As INVEGA SUSTENNA is excreted in breast milk, it is recommended that you do not breast-feed while you use INVEGA SUSTENNA.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any 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, pain-killers or some allergy medications 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.

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

How is it given

Using it for the first time

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).

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.

How much of it will be given

Your doctor will decide the strength of INVEGA SUSTENNA which is suitable for you.

How is it given

INVEGA SUSTENNA will be given to you by injection by a healthcare professional. It is a medicine designed to gradually release into your body so that you do not have to take this medicine every day.

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. 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.

Your doctor or healthcare provider will give you the injection into the upper arm or buttocks. You may feel some pain or discomfort, but this may become less over time.

How often it is given

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 many injections you will need

INVEGA SUSTENNA 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.

What if you miss a dose

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

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.

For patients with kidney problems

INVEGA SUSTENNA has not been studied in patients whose kidney is not functioning properly. Your doctor will decide the dose suitable for you.

For patients with mild kidney problems the recommended first dose is 100 mg and second dose is 75 mg one week later. Thereafter the recommended monthly dose is 50 mg.

Use of INVEGA SUSTENNA is not recommended in patients with moderate or severe kidney function impairment.

INVEGA SUSTENNA is not recommended for children under 18 years.

Overdose

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

However, if you experience any side effects after receiving INVEGA SUSTENNA, tell your doctor immediately or go to Accident and Emergency at your nearest hospital.

You may need urgent medical attention.

While you are using it

Things you must do

Follow your doctor's instructions carefully. Do not miss an injection or stop the treatment without consulting your doctor first.

Your doctor will be happy to discuss any questions you may have with your treatment.

Tell your doctor if you are pregnant or planning to become pregnant.

Tell your doctor immediately if you 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 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.

Tell any other doctors, dentists, and pharmacists who want to start you on any new medicines listed under 'Taking other medicines' (above) that you are taking INVEGA SUSTENNA.

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

Things you must not do

Do not miss any injections or any appointments with the doctor.

Do not drink alcohol.

INVEGA SUSTENNA can increase the effects of alcohol.

Things to be careful of

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.

Avoid driving or operating machinery until you are sure that INVEGA SUSTENNA does not affect your alertness.

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.

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.

Side Effects

All medicines may have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

All medicines can have side effects. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking INVEGA SUSTENNA.

It helps most people with symptoms of schizophrenia, but it may have unwanted side effects in a few people.

Tell your doctor if you notice any of the following and they worry you:

- **difficulty thinking, working or carrying out your usual daily activities because of:**
 - nausea
 - headache
 - trembling, muscle weakness, unsteadiness on your feet, lack of coordination or slow, shuffling walk
 - sleeplessness, drowsiness, tiredness or difficulty in concentrating
 - pain at injection site
- **behavioural changes such as:**
 - irritability or agitation
 - unusual anxiety or depression
 - unusually elated mood
 - lack of emotion
- **joint or movement changes such as:**
 - muscle stiffness or pain, bone or muscle ache
 - unusual restlessness, repetitive or involuntary movements

- unusual facial movements or a sustained upwards stare
- **other changes such as:**
 - unexplained increased in appetite
 - eye rolling
 - "flu-like" symptoms, cough, stuffy nose
 - urinary tract infection
 - toothache
 - inability to urinate or pain when passing urine
 - dry mouth, distorted taste sensation, drooling
 - acne
 - dry skin
 - nosebleeds
 - hardening of the skin
 - diarrhoea
 - vomiting, indigestion, heartburn, abdominal pain
 - breast swelling and/or unusual secretion of breast milk
 - missed or irregular menstrual periods
 - difficulty getting or maintaining an erection; or having continuous and/or painful erection

These are mild side effects of INVEGA SUSTENNA but may require medical attention.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- **signs of heart or blood pressure problems including:**
 - fall in blood pressure, blurry vision, light-headedness or dizziness particularly on standing that persists despite sitting or lying down
 - very fast heart rate, slowed heart rate, heart rhythm irregularities
- **body temperature changes such as:**
 - fever

- unexplained high body temperature, excessive sweating or rapid breathing
- **involuntary movements of the tongue, mouth, cheeks or jaw**
- **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 high blood sugar or diabetes such as unusual thirst, tiredness, upset stomach or need to urinate more often than usual**

These may be serious side effects of INVEGA SUSTENNA. You may need urgent medical attention.

Serious side effects are uncommon.

If any of the following happen, stop taking INVEGA SUSTENNA and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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. If you have them, you may have had a serious allergic reaction to INVEGA SUSTENNA
- 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, jaws, arms, legs or trunk (symptoms of tardive dyskinesia).

These may be very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice anything else that is making you feel unwell.

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

Do not hesitate to report any other side effects to your doctor or pharmacist.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using it

Storage

INVEGA SUSTENNA will be stored by your doctor or pharmacist. The injection is kept in a cool dry place, protected from light, where the temperature stays below 25°C.

Your doctor or pharmacist will not use it beyond the expiry date (month and year) printed on the pack.

Medicines cannot be stored indefinitely, even if stored properly.

Product Description

What it looks like

INVEGA SUSTENNA is available in prefilled syringes which contain different amounts of paliperidone (as palmitate). The pack also contains safety needles.

Ingredients

The active ingredient in INVEGA SUSTENNA is paliperidone (as palmitate).

The prefilled syringes contain either 25 mg, 50 mg, 75 mg, 100 mg or 150 mg of paliperidone (as palmitate).

Inactive ingredients are polysorbate 20, polyethylene glycol 4000, citric acid monohydrate, disodium hydrogen phosphate anhydrous, sodium dihydrogen phosphate monohydrate, sodium hydroxide, and water for injection.

Sponsor

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Registration Numbers

25 mg modified release aqueous suspension for intramuscular injection - AUST R 160858

50 mg modified release aqueous suspension for intramuscular injection - AUST R 160856

75 mg modified release aqueous suspension for intramuscular injection - AUST R 160859

100 mg modified release aqueous suspension for intramuscular injection - AUST R 160860

150 mg modified release aqueous suspension for intramuscular injection - AUST R 160857

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