

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 type 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 include skin rash, itching, shortness of breath, and/or swollen face.

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 patients.

Tell your doctor if you have or have ever had:

- heart or blood vessel diseases, including low or low blood pressure
- dehydration
- epilepsy, seizures
- suicide
- intraoperative iris syndrome (a complication that may occur during cataract extraction)
- disease of the pituitary gland
- inflammation of the lungs due to aspiration (the inhalation of food particles or fluids into the lungs)
- kidney or liver problems
- Dementia or Lewy Bodies dementia
- Parkinson's disease
- Neuroleptic Malignant Syndrome (a serious reaction to some medicines with a sudden increase in body temperature, extremely high blood pressure and severe convulsions)
- Tardive dyskinesia (a reaction to some medicines with involuntary

- movements of the tongue, face, mouth, jaws, arms, legs or trunk)
- diabetes
- disease of the blood vessels of the brain including stroke
- priapism (continuous erection) and/or painful erection
- 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 have been seen in patients taking Invega Sustenna. Blood clots in the lungs can be fatal

- low white blood cell count

As dangerously low numbers of certain types of white blood cells needed to fight infection in your blood has been seen very rarely with patients taking Invega Sustenna, your doctor may check your white blood cell counts. Tell your doctor 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).

Tell your doctor if:

- you are pregnant or are planning to become pregnant. Your doctor will advise you whether or not you should use Invega Sustenna. Shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding may occur in newborns, if you use Invega Sustenna in your last trimester of pregnancy.
- you are breast feeding. 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.

Tell your doctor if you are taking:

- sleeping tablets, tranquillisers, pain-killers, antihistamines
- medicines to treat depression, panic disorder, anxiety or obsessive-compulsive disorder
- medicines for your heart or blood pressure
- other medicines to treat mental illness or psychotic conditions.

How is it given

Using it for the first time

Treatment with Invega Sustenna will not be started by your doctor until it is known that you can tolerate oral paliperidone or oral / injectable risperidone.

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 they continue or worry you.

How much of it will be given

Your doctor will decide the dose suitable for you.

How is it given

Invega Sustenna is a modified release medicine that a healthcare professional will give you by injection. This means the medicine is released gradually into your body and 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 first 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.

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, 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 elderly patients

In general your doctor would prescribe the same dose as for adult patients, but he/she may adjust the dose if you have impaired kidney function.

For patients with impaired kidney function

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 function impairment 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 cannot be recommended for use in children with schizophrenia under 18 years at the present time as there is little experience with the product in this group.

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 being given 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 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 pregnant or are planning to become pregnant.

Tell your doctor immediately if you notice any worm-like movements of the tongue, or other uncontrolled movements of the tongue, mouth, cheeks or jaw which may progress to the arms and legs.

These are symptoms of a condition called tardive dyskinesia, which may develop in people taking antipsychotic medicines, including

Invega Sustenna. This condition is more likely to occur during long term treatment with Invega Sustenna, especially in elderly women. In very rare cases, this may be permanent. However, if detected early, these symptoms are usually reversible.

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking 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.

These include herbal treatments and those bought in a pharmacy or supermarket.

Be careful driving or operating machinery 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 or light-headed. If this occurs do not drive or operate machinery.

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.

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 or working because of:

- sleeplessness
- headache
- trembling
- drowsiness, tiredness, difficulty in concentrating
- pain at injection site

behavioural changes such as:

- agitation
- feeling anxious

other changes such as:

- muscle stiffness or pain, bone or muscle ache
- joint stiffness or swelling
- pneumonia
- infection
- blurry vision, eye rolling
- "flu-like" symptoms
- toothache
- inability to or pain when passing urine
- dry mouth
- lack of emotion
- depression
- acne
- dry skin
- elated mood

- vertigo
- nosebleeds
- hardening of the skin
- weight gain or weight loss
- increased or decreased appetite
- indigestion, nausea, abdominal pain
- diarrhoea
- vomiting
- excessive thirst
- unusual secretion of breast milk
- breast swelling
- missed or irregular menstrual periods
- difficulty getting or maintaining an erection; or having continuous and/or painful erection, priapism (prolonged erection)
- involuntary movements of the tongue, face, mouth, jaws, arms, legs or trunk. This could occur after taking Invega Sustenna or other antipsychotic medicines for a long time. Should this happen contact your doctor.

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:

heart or blood pressure problems such as:

- fall in blood pressure, particularly on standing. This will be apparent to you as light-headedness or dizziness that passes after a few seconds or after sitting down again
- faster heart rate, slowed heart rate, heart beat irregularities

body temperature changes such as:

- fever
- abnormally high body temperature

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).

These are 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 consumers.

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

Janssen-Cilag Pty Ltd

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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

This leaflet was prepared in January
2018.