

INVEGA HAFYERA®

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 HAFYERA?

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

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

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

Do not use if you have ever had an allergic reaction to paliperidone, risperidone 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 HAFYERA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with INVEGA HAFYERA 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 HAFYERA?

Your doctor or other healthcare professional will give the injection into the muscle in the buttock (gluteal intramuscular injection).

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

5. What should I know while using INVEGA HAFYERA?

Things you should do	- Remind any doctor or dentist 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. - Tell your doctor if you become pregnant or intend to become pregnant. - 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.
Things you should not do	Do not miss an injection or stop the treatment without consulting your doctor first.
Driving or using machines	INVEGA HAFYERA might affect your alertness and may affect your vision. You are, therefore, advised not to drive or operate machines before you know how sensitive you are to this medicine.
Drinking alcohol	Avoid drinking alcohol

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

6. Are there any side effects?

The side effects you may experience include: headache, drowsiness, pain at injection site, involuntary muscle movements, changes in body weight and symptoms of common cold such as coughing or stuffy nose or "flu-like" symptoms.

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 HAFYERA®

Active ingredient(s): *paliperidone palmitate*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using INVEGA HAFYERA?

INVEGA HAFYERA contains the active ingredient paliperidone palmitate. INVEGA HAFYERA belongs to the class of antipsychotic medicines and is used to treat schizophrenia in adults (18 years of age and older).

INVEGA HAFYERA is used after you have been treated with the 1-month injection for at least 4 months or the 3-month injection for at least one injection cycle. After your symptoms have been adequately treated with the 1-month or 3-month injection, INVEGA HAFYERA is used to keep the symptoms under control, i.e., to prevent its recurrence.

INVEGA HAFYERA injections are given once every 6 months.

Schizophrenia is a mental illness with symptoms such as hearing things, seeing or sensing things that are not there, mistaken beliefs, unusual suspiciousness, becoming withdrawn, incoherent speech, and reduced behavioral/emotional responses. People living with schizophrenia may also feel depressed, anxious, guilty, or tense.

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

Warnings

Do not use INVEGA HAFYERA if:

1. 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.
2. Always check the ingredients to make sure you can use this medicine.

Allergic reaction can be recognised for instance by skin rash, itching, shortness of breath or swollen face. If any of these occur, contact your doctor right away.

Check with your doctor if you:

- have any other medical conditions:
 - o Parkinson's disease or Dementia
 - o have ever been diagnosed with a condition whose symptoms include high temperature and muscle

stiffness (also known as Neuroleptic Malignant Syndrome)

- o have ever experienced abnormal movements of the tongue or face (Tardive Dyskinesia)
 - o are at risk for diabetes or high blood sugar
 - o have 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
 - o have epilepsy
 - o have or have had low white blood cell counts in your blood. Let your doctor know right away if you develop a fever or infection while being treated with INVEGA HAFYERA
 - o have a loss of kidney function. Your doctor may reduce your dose of INVEGA HAFYERA if your kidney function is reduced
 - o have a loss of liver function
 - o have prolonged and/or painful erection
 - o have had problems with body temperature regulation
 - o have 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 HAFYERA. Blood clots in the lungs can be fatal.
- Even for patients who have previously tolerated oral paliperidone or risperidone, allergic reactions have been reported very rarely after receiving the 1-month paliperidone palmitate injection product and it is possible that allergic reactions could occur with INVEGA HAFYERA.
 - Body weight changes have been seen in patients receiving antipsychotic medicines. Your doctor may monitor your body weight while you are being treated with INVEGA HAFYERA.
 - During an operation on the eye for cloudiness of the lens (cataract), the pupil (the black circle in the middle of your eye) may not increase in size as needed. Also, the iris (the coloured part of the eye) may become floppy during surgery and that may lead to eye damage. If you are planning to have an operation on your eye, make sure you tell your eye doctor that you are taking this medicine.
 - 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.

You should not take INVEGA HAFYERA during pregnancy unless this has been discussed with your doctor. Shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, or difficulty in feeding may occur in your newborn baby if you use INVEGA HAFYERA at any time during your pregnancy, and even if you used INVEGA HAFYERA before becoming pregnant.

- Do not breastfeed while you are being treated with INVEGA HAFYERA. Consult your doctor in that case.

Patients with kidney or liver impairment

- Your doctor may adjust your dose of INVEGA HAFYERA based upon your kidney function. INVEGA HAFYERA 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 HAFYERA is being considered for use in a patient with severe liver impairment.

Elderly Patients

INVEGA HAFYERA 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 HAFYERA is not for treating people with schizophrenia who are younger than 18 years old.

3. What if I am taking other medicines?

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

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 increase the levels of paliperidone in your blood, which may produce an increase in side effects resembling overdose of INVEGA HAFYERA
- Since INVEGA HAFYERA can make you sleepy or drowsy, care should be taken when INVEGA HAFYERA is taken with other medicines that can also cause sleepiness or drowsiness.
- Since INVEGA HAFYERA can lower blood pressure, care should be taken when INVEGA HAFYERA is taken with other medicines that lower blood pressure.
- INVEGA HAFYERA can reduce the effect of medicines against Parkinson's disease and restless legs syndrome (e.g., levodopa).
- INVEGA HAFYERA should be used with caution with medicines that increase the activity of the central nervous system (psychostimulants such as methylphenidate).

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 HAFYERA.

4. How do I use INVEGA HAFYERA?

How much to use

- The first dose of INVEGA HAFYERA is determined by your doctor or healthcare professional based on your existing dose for 1-month injection product (INVEGA SUSTENNA) or 3-month injection product (INVEGA TRINZA)
- INVEGA HAFYERA is given by injection into the muscle of your buttock once every 6 months. Depending on your symptoms, your doctor may increase or decrease

the dose of medicine you receive at the time of your scheduled injection.

When to use INVEGA HAFYERA

- INVEGA HAFYERA is only used after you have been treated with the 1-month injection product (INVEGA SUSTENNA) for at least 4 months or the 3-month injection (INVEGA TRINZA) for at least one injection cycle.
- Like the 1-month and the 3-month injection, INVEGA HAFYERA 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 important not to miss your scheduled dose.

If you forget to use INVEGA HAFYERA

- If you cannot keep your appointment with the doctor, make sure you call your doctor right away so another appointment can be made as soon as possible. Your doctor may also want to see you even if you are not scheduled for an injection of INVEGA HAFYERA.

If you use too much INVEGA HAFYERA

This medicine will be given to you under medical supervision; it is, therefore, unlikely that you will be given too much.

Patients who have been given too much paliperidone may experience the following symptoms: drowsiness or sleepiness, fast heart rate, low blood pressure, an abnormal electrocardiogram (electrical tracing of the heart), or slow or abnormal movements of the face, body, arms, or legs.

Because INVEGA HAFYERA 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 HAFYERA.

If you experience the above symptoms, you should immediately contact your doctor.

5. What should I know while using INVEGA HAFYERA?

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.

Tell your doctor if you become pregnant or intend to become pregnant.

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 HAFYERA. 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 or dentist you visit that you are using INVEGA HAFYERA.

Things you should not do

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

Driving or using machines

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

INVEGA HAFYERA might affect your alertness and may affect your vision. You are, therefore, advised not to drive or operate machines before you know how sensitive you are to this medicine.

Drinking alcohol

Alcohol should be avoided when taking INVEGA HAFYERA.

Looking after your medicine

- INVEGA HAFYERA is stored and administered by healthcare professionals so it is unlikely that you will store this medicine at home. If you do,
 - store below 25°C in a horizontal position. See arrows on product carton for proper orientation.
 - 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.

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

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: - 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 side effects

Less serious side effects	What to do
- 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 elevated mood movement changes such as: - muscle or joint stiffness or pain, bone or muscle ache - unusual restlessness - unusual facial movements with sustained upwards stare other changes such as: - unexplained increase in appetite or weight gain - weight loss - common cold such as coughing or stuffy nose or "flu-like" symptoms - urinary tract infection - eye rolling - toothache - dry mouth, distorted taste sensation, drooling - acne - dry skin - hardening of the skin - nosebleeds - vomiting, indigestion, nausea, abdominal pain - diarrhoea - constipation - unusual secretion of breast milk - breast swelling - missed or irregular menstrual periods - difficulty getting or maintaining an erection	

Serious side effects

Serious side effects	What to do
Severe allergic reaction 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 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	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.

- very fast heart rate, slowed heart rate, heart rhythm irregularities

signs of high blood sugar or diabetes such as:

- being thirsty all the time, having to urinate or "pass urine" more often than usual, or feeling weak or hungry.

liver related:

- yellowing of skin (jaundice)

Other changes such as:

- inability to or pain when passing urine
- having continuous and/or painful erection (priapism)
- 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).
- 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)
- fever, muscle stiffness, sweating or a lowered level of consciousness (symptoms of neuroleptic malignant syndrome).

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 HAFYERA looks like

INVEGA HAFYERA is available as a white to off-white coloured suspension in pre-filled syringes for intramuscular use in the strengths listed below:

- paliperidone 700 mg equivalent to paliperidone palmitate 1092 mg (AUST R 354080).
- paliperidone 1000 mg equivalent to paliperidone palmitate 1560 mg (AUST R 354090).

Who distributes INVEGA HAFYERA

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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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 HAFYERA contains

Active ingredient (main ingredient)	Paliperidone (as palmitate)
Other ingredients (inactive ingredients)	citric acid monohydrate macrogol 4000 polysorbate 20