

Consumer Medicine Information

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such as hearing things, seeing or sensing things that are not there, mistaken beliefs, unusual suspiciousness, becoming withdrawn, incoherent speech, and reduced behavioral/emotional responses.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:
 - Parkinson's disease or Dementia
 - have ever been diagnosed with a condition whose symptoms include high temperature and muscle stiffness (also known as Neuroleptic Malignant Syndrome)

- have ever experienced abnormal movements of the tongue or face (Tardive Dyskinesia)
- are at risk for diabetes or high blood sugar
- 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
- have epilepsy
- 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
- have a loss of kidney function. Your doctor may reduce your dose of INVEGA HAFYERA if your kidney function is reduced
- have a loss of liver function
- have prolonged and/or painful erection
- have had problems with body temperature regulation
- 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?