EMA/104449/2024
EMEA/H/C/006185

Niapelf (*paliperidone*)

An overview of Niapelf and why it is authorised in the EU

What is Niapelf and what is it used for?

Niapelf is an antipsychotic medicine used for the maintenance treatment of schizophrenia in adults whose disease has already been stabilised on treatment with paliperidone or risperidone.

Some patients whose symptoms have not yet been stabilised may still be given Niapelf if they have responded well to oral (by mouth) paliperidone or risperidone in the past, their symptoms are mild to moderate and a long-acting injectable treatment is needed.

Niapelf is a 'generic medicine'. This means that Niapelf contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU. The reference medicine for Niapelf is Xeplion. For more information on generic medicines, see the question-and-answer document here.

Niapelf contains the active substance paliperidone.

How is Niapelf used?

Niapelf is available as a prolonged-release suspension for injection in prefilled syringes. Prolonged-release means that the active substance is released slowly over a few weeks after being injected.

Treatment with Niapelf starts with two injections, given one week apart, followed by monthly maintenance injections. The first two injections are given into the deltoid muscle (upper part of the arm), while the maintenance doses can be given in the gluteal muscle (buttocks) or the deltoid muscle.

The medicine can only be obtained with a prescription.

For more information about using Niapelf, see the package leaflet or contact your doctor or pharmacist.

How does Niapelf work?

The active substance in Niapelf, paliperidone, is an active metabolite (breakdown product) of risperidone, another antipsychotic medicine that has been used in the treatment of schizophrenia since the 1990s. In the brain, paliperidone attaches to several different receptors (targets) on nerve cells. This disrupts signals transmitted between brain cells by neurotransmitters, chemicals that allow nerve

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

cells to communicate with each other. Paliperidone acts mainly by blocking receptors for the neurotransmitters dopamine and 5-hydroxytryptamine (also called serotonin), which are involved in schizophrenia. By blocking these receptors, paliperidone helps to normalise the activity of the brain and reduce symptoms of the disease.

Paliperidone has been authorised in the European Union as Invega since 2007, as an oral treatment for schizophrenia. In Niapelf, paliperidone has been attached to a fatty acid that allows it to be released slowly after being injected. This allows the injection to have a long duration of action.

How has Niapelf been studied?

Studies on the benefits and risks of the active substance in the authorised use have already been carried out with the reference medicine, Xeplion, and do not need to be repeated for Niapelf.

As for every medicine, the company provided studies on the quality of Niapelf. The company also carried out studies that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What are the benefits and risks of Niapelf?

Because Niapelf is a generic medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Niapelf authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Niapelf has been shown to have comparable quality and to be bioequivalent to Xeplion. Therefore, the Agency's view was that, as for Xeplion, the benefits of Niapelf outweigh the identified risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Niapelf?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Niapelf have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Niapelf are continuously monitored. Suspected side effects reported with Niapelf are carefully evaluated and any necessary action taken to protect patients.

Other information about Niapelf

Niapelf received a marketing authorisation valid throughout the EU on 21 March 2024.

Further information on Niapelf can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/niapelf. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 04-2024.