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Yeytuo (*lenacapavir*)

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

What is Yeytuo and what is it used for?

Yeytuo is a medicine used for preventing sexually transmitted HIV-1 infection (pre-exposure prophylaxis or PrEP) in adults and adolescents weighing at least 35 kg who are at increased risk of becoming infected. It should be used in combination with safer sex practices, such as using condoms.

Yeytuo contains the active substance lenacapavir.

How is Yeytuo used?

Yeytuo can only be obtained with a prescription and should be prescribed by a healthcare professional who has experience in the management of HIV prevention.

Yeytuo is a combined treatment consisting of tablets to be taken by mouth and a solution for injection. Yeytuo injections are given at the start of treatment (day 1), and every 6 months thereafter. In addition, people need to take Yeytuo tablets on days 1 and 2. The injections are given under the skin in the abdomen (belly) or thigh by a doctor or nurse.

Before starting treatment and before each injection, tests must be performed to ensure that the person does not have an HIV-1 infection. Healthcare professionals should also ensure the person agrees to keep to the treatment schedule and should explain why this is important.

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

How does Yeytuo work?

The active substance in Yeytuo, lenacapavir, attaches to proteins that make up the shell around the HIV-1 virus genetic material (the capsid). By binding to these proteins, lenacapavir interferes with steps needed for the virus to multiply. This will reduce the risk of the virus multiplying and spreading throughout the body if a person is exposed to the virus.

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What benefits of Yeytuo have been shown in studies?

Two main studies compared the effectiveness of Yeytuo with that of another medicine authorised for PrEP, Truvada (emtricitabine/tenofovir disoproxil). All study participants tested negative for HIV infection at the start of the studies.

The first study involved sexually active adult and adolescent women from 16 to 25 years of age. No new HIV infections occurred in the group of 2,134 (0%) people who received Yeytuo, compared with 16 new infections in the group of 1,068 (1.5%) people given Truvada.

The second study involved sexually active adult and adolescent men and gender-diverse persons (transgender and gender nonbinary individuals) from 16 years of age. Two new HIV infections occurred in the group of 2,179 (0.1%) people who received Yeytuo, compared with 9 in the group of 1,086 (0.8%) people given Truvada.

What are the risks associated with Yeytuo?

For the full list of side effects and restrictions with Yeytuo, see the package leaflet.

The most common side effects with Yeytuo injections (which may affect more than 1 in 10 people) are reactions at the site of injection including nodules (small lumps), pain, swelling, induration (hardening), erythema (redness) and pruritus (itching) at the injection site.

Yeytuo must not be used in people who have not been tested for HIV infection or who are positive for HIV infection. Yeytuo must also not be used together with some other medicines that may reduce the levels of Yeytuo in the body, such as rifampicin, carbamazepine, phenytoin or the herbal product St. John's wort.

Why is Yeytuo authorised in the EU?

The main studies showed that Yeytuo is effective at preventing sexually transmitted HIV infection and it is well tolerated overall. The twice-yearly Yeytuo injection may help people keep to their PrEP routine, compared with other PrEP options that require daily dosing.

The European Medicines Agency therefore decided that Yeytuo's benefits are greater than its risks and it can be authorised for use in the EU.

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

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

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

Other information about Yeytuo

Yeytuo received a marketing authorisation valid throughout the EU on 25 August 2025.

Further information on Yeytuo can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/yeytuo.

This overview was last updated in 08-2025.