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Lenacapavir Gilead (*lenacapavir*)

An overview of Lenacapavir Gilead and why it received a positive opinion

What is Lenacapavir Gilead and what is it used for?

Lenacapavir Gilead 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.

Lenacapavir Gilead is intended for use outside the EU. An identical medicine, Yeytuo, is authorised in the EU.

Lenacapavir Gilead contains the active substance lenacapavir.

How is Lenacapavir Gilead used?

Lenacapavir Gilead is a combined treatment consisting of tablets to be taken by mouth and a solution for injection. Lenacapavir Gilead injections are given at the start of treatment (day 1) and every 6 months thereafter. In addition, people need to take Lenacapavir Gilead 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.

Arrangements for supply of this medicine will be the responsibility of national medicines regulators.

For more information about using Lenacapavir Gilead, see the package leaflet or contact your healthcare provider.

How does Lenacapavir Gilead work?

The active substance in Lenacapavir Gilead, 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 Lenacapavir Gilead have been shown in studies?

Two main studies compared the effectiveness of Lenacapavir Gilead 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 Lenacapavir Gilead, 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 Lenacapavir Gilead, compared with 9 new infections in the group of 1,086 (0.8%) people given Truvada.

What are the risks associated with Lenacapavir Gilead?

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

The most common side effects with Lenacapavir Gilead 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.

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

Why did Lenacapavir Gilead receive a positive opinion?

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

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) therefore concluded that the benefits of the medicine outweigh its risks and issued a positive scientific opinion.

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

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

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

Other information about Lenacapavir Gilead

The European Medicines Agency gave a positive opinion for Lenacapavir Gilead on 24 July 2025.

The Agency assessed Lenacapavir Gilead as part of its cooperation with the World Health Organization, whereby the Agency evaluates medicines that are not intended for use in the EU but are needed to prevent or treat diseases of major public health importance around the world.

Further information on Lenacapavir Gilead can be found on the Agency's website: ema.europa.eu/en/opinion-medicine-use-outside-EU/human/lenacapavir-gilead.

This overview was last updated in 08-2025.