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Sunlenca (*lenacapavir*)

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

What is Sunlenca and what is it used for?

Sunlenca is used, together with other medicines, to treat adults infected with human immunodeficiency virus type 1 (HIV-1), a virus that causes acquired immune deficiency syndrome (AIDS). Sunlenca is given when the virus is resistant to other treatments.

Sunlenca contains the active substance lenacapavir.

How is Sunlenca used?

Sunlenca is available as tablets to be taken by mouth and as a solution for injection. Sunlenca tablets are taken at the start of the treatment, on days 1, 2 and 8. One week after that, patients are given Sunlenca injections every 26 weeks as maintenance treatment. Injections are given under the skin by a doctor or nurse.

Before starting treatment, the doctor must ensure that the patient agrees to keep to the schedule of injections and should explain why this is important. The treatment schedule helps keep the virus under control. If a patient misses treatment doses, virus levels may increase, or the virus may become resistant to treatment. If treatment with Sunlenca is stopped, another treatment to suppress the virus must be started.

Sunlenca can only be obtained with a prescription and should be prescribed by a doctor who has experience in the management of HIV infection.

For more information about using Sunlenca, including the schedule for the injections, see the package leaflet or contact your doctor or pharmacist.

How does Sunlenca work?

The active substance in Sunlenca, lenacapavir, is a substance that binds to the proteins that make up the outer layer of the HIV-1 virus (the capsid). By binding to these proteins, Sunlenca interferes with different steps that are necessary for the virus to multiply. This reduces the amount of HIV in the blood and keeps it at a low level. Sunlenca does not cure HIV infection or AIDS, but it can hold off damage to the immune system and the development of infections and diseases associated with AIDS.

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What benefits of Sunlenca have been shown in studies?

Sunlenca, taken together with other treatments to control HIV-1 infection, was effective at reducing the amount of HIV-1 virus in the blood (viral load) in one main study involving adults who had already tried other treatments and who did not respond or were no longer responding to most of the medicines used to control HIV-1 infection. In the first two weeks of the study, patients were given Sunlenca or placebo (a dummy treatment) in addition to their usual HIV medicines. After this time, 87.5% (21 out of 24) of the participants who were given Sunlenca showed a meaningful decrease in viral load, compared with 16.7% (2 out of 12) of the participants who were given a placebo. The 12 patients first given placebo then also received Sunlenca, and all 36 patients were given maintenance injections every 26 weeks. Viral load was under 50 copies of the virus per mL (which is a threshold considered indicative of durable clinical and immunological benefits) in 80.6% (29 out of 36) of patients after 26 weeks, and in 83.3% (30 out of 36) of patients after 52 weeks of treatment.

What are the risks associated with Sunlenca?

The most common side effects with Sunlenca (which may affect more than 1 in 100 people) are reactions at the injection site and nausea.

For the full list of side effects of Sunlenca, see the package leaflet.

Why is Sunlenca authorised in the EU?

Sunlenca is a new type of treatment for controlling HIV-1 infection, which was effective at reducing viral load in patients with infections that are resistant to other treatments. These patients often lack options to manage their infection, and Sunlenca is considered to address an unmet medical need for this population. The side effects of Sunlenca are considered manageable.

Therefore, the European Medicines Agency decided that Sunlenca'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 Sunlenca?

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

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

Other information about Sunlenca

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