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Sunlenca® (active substance: lenacapavir)

First authorisation in Switzerland: 7 July 2023

Medicinal product for the treatment of infections with type 1 human immunodeficiency virus (HIV-1) in adults

About the medicinal product

The medicinal product Sunlenca contains the active substance lenacapavir as lenacapavir sodium.

Sunlenca is a medicinal product for the treatment of adults infected with type 1 human immunodeficiency virus (HIV-1). This is a life-threatening infection and causes acquired immunodeficiency syndrome (AIDS).

The medicinal product Sunlenca is used in combination with other antiretrovirals[1] to treat heavily treatment-experienced adults with multi-drug resistant HIV-1 infection whose current antiviral therapy has to be adjusted due to resistance, intolerance, or safety concerns.

Sunlenca helps control, but cannot cure, the HIV infection.

Mode of action

Lenacapavir is an inhibitor[2] of HIV-1 capsid function. The capsid is a protein shell that surrounds the HIV genetic material. The active substance lenacapavir inhibits the functions of this protein shell in virus replication.

The active substance lenacapavir interferes in several key steps in the viral life cycle. It blocks the binding of specific proteins to the capsid, thereby preventing the HIV-1 DNA from entering the nucleus. Lenacapavir also inhibits viral development and release.

This mechanism of action inhibits the production and release of HIV virus, thereby controlling the infection.

[1] Antiretroviral: This type of medicinal product targets retroviruses whose genetic material is contained in RNA. The HI virus is a retrovirus.

[2] An inhibitor slows, inhibits, or prevents one or more chemical or biochemical reactions.

Administration

Sunlenca, containing the active substance lenacapavir, is available on prescription as a solution for injection at a dose of 463.5 mg/1.5 mL and as film-coated tablets at a dose of 300 mg.

Treatment is administered by a doctor who has experience in treating HIV infections.

On Treatment Days 1 and 2, the recommended dose of Sunlenca is 600 mg per day, taken as film-coated tablets. On Day 8, the recommended dose is 300 mg, taken as film-coated tablets. On Day 15, the recommended dose is 927 mg, administered as 2 injections under the skin of the abdomen (subcutaneous).

During maintenance therapy, the recommended dose is 927 mg of Sunlenca administered as a subcutaneous injection once every 6 months from the date of the last injection.

The film-coated tablets can be taken with or without food. The film-coated tablets should not be chewed, crushed, or split.

The doctor explains the importance of compliance for optimised therapy to the patient in order to reduce the risk of potential development of resistance.

Efficacy

The efficacy of Sunlenca was investigated in the CAPELLA study in a total of 72 heavily treatment-experienced adult patients with multi-drug resistant HIV-1 infection over a period of 52 weeks.

The efficacy of Sunlenca was investigated versus placebo (dummy drug). In addition, Sunlenca or the placebo was combined with an optimised background regimen.

The study found that patients who received Sunlenca had a lower viral load (reduction in HIV-1 virus in the blood) than study participants who received the placebo instead of Sunlenca.

Precautions, undesirable effects, & risks

Sunlenca must not be used in those who are hypersensitive to the active substance or any of the excipients.

The most common undesirable effects are reactions at the injection site and nausea.

All precautions, risks, and other possible side effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

Treatment of patients with multi-drug resistant HIV-1 infection is complex and challenging. There is a medical need for new treatment options for these patients.

Sunlenca offers a new mode of action versus current antiretrovirals.

The pivotal study showed that patients who received Sunlenca in addition to an optimised background regimen had a lower viral load in the blood and thus benefited from treatment.

Taking all the risks and precautions into account, and based on the available data, the benefits of Sunlenca outweigh the risks.

Swissmedic has therefore approved the medicinal product Sunlenca, containing the active substance lenacapavir, in Switzerland for the treatment of heavily treatment-experienced patients infected with multi-drug resistant HIV-1.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Sunlenca®

Information for patients (package leaflet): Information for patients Sunlenca®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

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