GILEAD | Medical Information

SUNLENCA® (lenacapavir)

What are the possible side effects of SUNLENCA?

This information is provided in response to your question. It is not treatment advice on how to use SUNLENCA. Please discuss this question and others you have about your medical condition or treatment with your healthcare provider.

Download the SUNLENCA Patient Information for more details, including approved use(s) and important warnings: https://www.gilead.com/-/media/files/pdfs/medicines/hiv/sunlenca/sunlenca_patient_pi.pdf

The short answer[1]

- The **most common side effects** of SUNLENCA during clinical trials were **nausea and injection site reactions**. Each of these side effects affected at least 3 out of 100 people. Nausea was experienced by 4 in every 100 people and injection site reactions were experienced by 65 in every 100 people in SUNLENCA clinical studies.

- SUNLENCA may cause **serious side effects** such as:

  - **Changes in your immune system,** or immune reconstitution syndrome, can happen when you start taking HIV-1 medicines.

  - **Injection site reactions,** may happen when you receive SUNLENCA injections and may include swelling, pain, redness, skin hardening, small mass or lump, and itching.

- These are not all the possible side effects of SUNLENCA. Please tell your healthcare provider if you have any side effects.

Who is SUNLENCA for?[1]

SUNLENCA is a **prescription medicine** that is used **with other human immunodeficiency virus-1 (HIV-1) medicines** to treat HIV-1 infection in adults:

- who have received HIV-1 medicines in the past, **and**
- who have HIV-1 virus that is resistant to many HIV-1 medicines, **and**
- whose current HIV-1 medicines are failing. Your HIV-1 medicines may be failing because the HIV-1 medicines are not working or no longer work, you are not able to tolerate the side effects, or there are safety reasons why you cannot take them.

What are the common side effects[1]?

The most common side effects of SUNLENCA in clinical trials were nausea and injection site reactions.

- Each of these side effects happened in at least 3 out of 100 adults. Nausea was experienced by 4 in every 100 people and injection site reactions were experienced by 65 in every 100 people in SUNLENCA clinical studies.

What are the serious side effects[1]?

SUNLENCA may cause **serious side effects** such as:

- **Changes in your immune system**, or immune reconstitution syndrome, can happen when you start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider right away if you have any new symptoms after starting your HIV-1 medicine.

- **Injection site reactions** may happen when you receive SUNLENCA injections and may include swelling, pain, redness, skin hardening, small mass or lump, and itching. Hardened skin or lumps at the injection site usually can be felt but not seen. If you develop hardened skin or a lump, it may take longer than other reactions at the injection site to go away, and the injection site may not completely heal on its own. Tell your healthcare provider if you have any injection site reactions.

Where can I get more information on the side effects of SUNLENCA?

To date, most of the information on the side effects of SUNLENCA is from clinical trials. Before a medicine is approved by the US Food and Drug Administration or FDA, researchers do clinical trials in groups of patients to see if the medicine works and how safe it is. Clinical trials are carried out in hospitals and clinics, and only some patients are eligible to take part. This means that the side effects seen in clinical trials may not be exactly the same as the side effects that people experience in the “real world”.

Clinical trials give us a very good idea of the most common or serious side effects that a medicine causes. However, they may not find all of the side effects that a medicine can cause.

Please talk to your healthcare provider if you have a side effect that is bothering you or that is not going away.

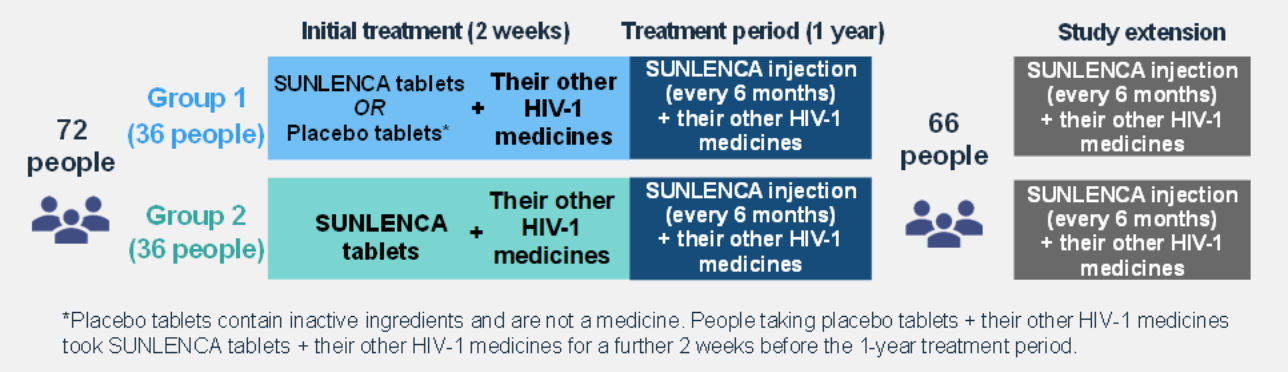
What were the additional side effects in SUNLENCA clinical trials?

CAPELLA TRIAL

Study Plan[2]

The CAPELLA trial studied how well the medication SUNLENCA worked when combined with other HIV-1 treatments in 72 adults who have received HIV-1 medicines in the past and whose HIV-1 is resistant to multiple HIV-1 medicines.

Adults started on SUNLENCA tablets for two weeks, followed by SUNLENCA injections on Day 15. These injections were then repeated every six months in addition to their other prescribed HIV-1 medicines.



Results

Here is what the study found:

- **Overall side effects[2]:**
  - Through 3 years, the **most common side effects** reported in at least 15 out of 100 people were diarrhea, nausea, urinary tract infection, and cough.
  - Two people stopped taking SUNLENCA because of side effects through 3 years.
- **Injection site reactions[3]:**
  - Injection site reactions occurred in about:

First injection: 63 out of 100 people after the first injection

Second injection: 46 out of 100 people after the second injection

Third injection: 55 out of 100 people after the third injection

- At 3 years, most of the injection site reactions were mild to moderate in severity and happened less often over time; two people stopped taking SUNLENCA because of injection site nodules (a small hard bump that can form under the skin)[2].

What side effects have been seen after SUNLENCA clinical trials?

After a drug is approved by the FDA, information on the side effects that the drug causes in the “real world” is collected. Because of the way this information is collected, it is not always possible to know for sure how common these side effects are, or if they are caused by the drug.

Damage or death of the skin or tissue at the injection site, also known as injection site necrosis, has been reported in people taking SUNLENCA in the real-world setting; however, it is not known how many people have experienced this side effect.[1]

Glossary

Clinical trial: a study in people. They may help to find out how well a medicine works or how safe it is.

Diarrhea: frequent, loose watery stools, which can cause dehydration and may require hospitalization and treatment with intravenous fluids.

FDA (Food and Drug Administration): is a government agency within the U.S. Department of Health and Human Services that oversees the Nation's public health by making sure that human and veterinary drugs, vaccines, biological products, medical devices, cosmetics, dietary supplements, the food supply, and any products that give off radiation are safe, effective, and secure.

HIV-1 (Human Immunodeficiency Virus type 1): is a virus that attacks the body’s immune system. If this is not treated, it can lead to AIDS (acquired immunodeficiency syndrome).

Immune system: your body’s defense team. It protects you from germs like bacteria and viruses that can make you sick. It is like an army made up of different types of cells and proteins that work together to find and destroy harmful invaders and keep you healthy.

Injection site necrosis: damage or death of the skin or tissue at the injection site.

Nausea: feeling sick to the stomach; stomach discomfort and the sensation of wanting to vomit.

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Placebo: in a clinical trial, a placebo is made to look like the investigational treatment, but does not have any treatment in it. It is sometimes used to compare against the actual investigational treatment to evaluate effectiveness.

Resistant: when a disease or infection is "resistant" to a medication, it means that the medication does not work well to fight the infection anymore.

SUNLENCA: a tablet that contains lenacapavir. It is approved to treat HIV infection in people who are heavily treatment-experienced.

Urinary tract infection: an infection in any part of your urinary system — your kidneys, ureters, bladder, and urethra.

References

1. Enclosed, Gilead Sciences Inc. SUNLENCA® (lenacapavir) tablets, for oral use. SUNLENCA® (lenacapavir) injection, for subcutaneous use. U.S. Prescribing Information. Foster City, CA.
2. Ogbuagu O, McGowan JP, Stapleton A, et al. Long-Acting Subcutaneous Lenacapavir in People With Multi-Drug-Resistant HIV-1: 3-Year Results of the CAPELLA Study.[Presentation #155]. Paper presented at: IDWeek 2024; October 16-19, 2024; Los Angles, CA.
3. Castagna A, Arevalo JLB, Jean-Michel M, et al. Follow-Up of Injection Site Reactions in Clinical Studies of People Using Lenacapavir Every 6 Months for HIV Treatment.[Poster: eP.A.104]. Paper presented at: The 19th European AIDS Conference; October,18–21, 2023,; Warsaw, Poland.

More information about SUNLENCA

If you would like more detailed information about SUNLENCA, please visit:
https://www.gilead.com/-/media/files/pdfs/medicines/hiv/sunlenca/sunlenca_pi.pdf

This is the US FDA-approved Prescribing Information, including the Patient Labeling, for SUNLENCA. It will tell you about the uses, warnings, and other important safety information about SUNLENCA.

Important note

Gilead Sciences, Inc. is providing this letter in response to your unsolicited request for medical information. Some of the information included in this letter may not be covered in the US FDA-approved Prescribing Information for SUNLENCA. Gilead Sciences, Inc. does not intend this letter to be used as medical advice and does not promote use of SUNLENCA in a way that has not been approved by the FDA. Please discuss this question and others you may have about your medical condition or treatment with your healthcare provider.

Follow-Up

For any additional questions, please contact Gilead Medical Information at:
☎1-866-MEDI-GSI (1-866-633-4474) or https://www.patient.askgileadmedical.com/

Reporting side effects

Please report all adverse events to:
Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or
www.gilead.com/utility/contact/report-an-adverse-event

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or www.accessdata.fda.gov/scripts/medwatch

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