

Sunlenca (lenacapavir for HIV treatment)

Summary

Sunlenca is the name given to the tablets and the injectable formulation of the anti-HIV drug lenacapavir. This drug belongs to a group or class of drugs called capsid inhibitors.

Sunlenca is meant for adults with HIV whose current regimen is not working and who have used many regimens in the past and who have HIV that is resistant to many other treatments.

Sunlenca is initially taken as a mix of tablets and injections. The injections are given by a healthcare provider. The drug is injected just under the skin in the belly. After initial dosing, subsequent doses of Sunlenca are given every six months (26 weeks) via injection. There is no need to take tablets of Sunlenca in the future if injection appointments are on schedule. Sunlenca is meant to be used together with other anti-HIV drugs.

Sunlenca is generally well-tolerated, side effects are usually mild to moderate and temporary – headache, diarrhea and nausea.

How does Sunlenca work?

Sunlenca works by interfering with a protein called the capsid, which is used by HIV-infected cells. This protein protects HIV's genetic information. Sunlenca can attack this protein at multiple points as the virus moves through the cell.

FACT SHEET

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How do people with HIV use Sunlenca?

Starting treatment with Sunlenca may seem complicated but once you move beyond the starting phase, it gets easier. When starting treatment with Sunlenca, two pills (300 mg each) of Sunlenca are taken on the first day, followed by two pills on the second day. On the eighth day of Sunlenca initiation, just one pill is taken. Sunlenca can be taken with or without food.

On the 15th day after initiating Sunlenca, a healthcare provider will give you two injections of Sunlenca just under the skin of your belly (abdomen).

After this, if you are on time for your next injections (in 26 weeks) and all subsequent injections, you will never need to take Sunlenca in pill form again.

While taking Sunlenca, you will also be taking other anti-HIV drugs that your doctor has prescribed.

For more information about HIV treatment, see CATIE's *Your Guide to HIV Treatment*.

For many people with HIV, the use of ART (HIV treatment or antiretroviral therapy) has increased their CD4+ cell counts and decreased the amount of HIV in their blood (viral load). These beneficial effects help to greatly reduce the risk of developing a life-threatening infection or an AIDS-related cancer. Sunlenca or any other treatment regimen (ART) is not a cure for HIV. It is therefore important that you see your doctor for checkups and lab tests on a regular basis.

Evidence shows that HIV-positive people who are on ART, engaged in care, and have an ongoing undetectable viral load are substantially less likely to transmit HIV to others, be it through sex, when sharing equipment to use drugs or during pregnancy and birth. In fact, the evidence for sexual transmission shows that people on ART who maintain an undetectable viral load do not pass HIV to their sexual partners. For further information see the CATIE fact sheet *HIV treatment and an undetectable viral load to prevent HIV transmission*. However, it may still be a good idea to use condoms because they can reduce your risk for getting and passing on other sexually transmitted infections.

Warnings

Infections and other complications

As mentioned earlier, Sunlenca is meant for people with HIV who have used many anti-HIV drugs in the past, whose current combination or regimen is failing and who have HIV that is resistant to many drugs. Such people usually have relatively low levels of CD4+ cells and this puts them at risk for serious AIDS-related infections and inflammatory complications. The manufacturer of Sunlenca, Gilead Sciences, recommends that people who use Sunlenca receive “close clinical observation by a healthcare professional experienced in the treatment of these associated HIV diseases.” The risk of such complications falls as CD4+ cell counts rise over time, particularly if they are consistently greater than 200 cells/mm³.

Minimizing resistance from HIV

It is important that you attend regular visits to your clinic and doctor – in particular, keeping appointments every 26 weeks for injections of Sunlenca. If you feel that you cannot meet your next injection appointment, let your clinic know right away so that a new appointment can be scheduled. Gilead indicates that there is some flexibility between dosing (plus or minus 2 weeks around each series of injections of Sunlenca). If doses are missed or skipped beyond that period, then there is a risk that HIV can develop mutations. These are changes in the virus that allow it to overcome the effects of Sunlenca and other treatments.

Special populations

Pregnancy

Sunlenca has not been studied in a large number of pregnant people with HIV. Gilead advises that “Sunlenca should only be used during pregnancy if the potential benefit justifies the potential risk to the fetus.”

People aged 65 and older

Sunlenca has not been tested in large numbers of people with HIV who are aged 65 and older. The safety of the drug in this population is not known.

Liver health

Gilead states that no dose adjustment of Sunlenca is required “in patients with mild or moderate hepatic impairment (Child-Pugh Class A or B).” Note that Sunlenca has not been studied in people with more serious liver injury – graded as Child-Pugh C. In such patients, Gilead states that the drug “should be administered with caution.”

Kidney health

Gilead sciences notes that “no dose adjustment of Sunlenca is required in patients with mild, moderate, or severe [kidney] impairment.” Sunlenca has not been studied in people with end-stage renal disease (ESRD). Gilead states, “therefore it should be administered with caution in these patients.”

General side effects

In clinical trials, side effects of Sunlenca included:

- headache
- nausea
- vomiting
- diarrhea
- muscle soreness
- rash

In most people, these side effects were mild to moderate and temporary. If you have persistent or bothersome symptoms, talk to your healthcare provider about them. Pharmacists are also a good source of information for coping with side effects.

Injection-related side effects

Sunlenca is administered by a healthcare professional every six months through injections just under the skin in the belly. It is normal to have

temporary injection site reactions, such as the following:

- redness
- swelling
- pain

These symptoms are usually mild to moderate.

Some people can develop small bumps or nodules at the injection site. These should resolve after a week or two. If nodules persist, speak to your doctor. The frequency and size of these nodules should diminish over time – with repeated injections.

Drug interactions

Some drugs (including prescribed and over-the-counter), herbs and supplements can interfere with the absorption and/or effectiveness of either Sunlenca tablets or injectable formulation. This interference is called a drug interaction. Some drugs or herbs and supplements can reduce the levels of the medicines in your blood. This can make Sunlenca less effective and lead to treatment failure, reducing your future treatment options. Other drugs can raise the levels of Sunlenca in your blood, resulting in enhanced side effects or new side effects. Therefore, it is important to disclose to your doctor, nurse and pharmacist all the supplements, drugs, and herbs you are taking.

This factsheet is *not* comprehensive and only lists some of the potential and actual drug interactions with Sunlenca. Speak to your pharmacist to find out more about drug interactions with Sunlenca

Drug interactions with Sunlenca

People taking Sunlenca should **not** use the following drugs:

- antiseizure drugs – carbamazepine, and phenytoin
- herbs/supplements – St. John’s wort or its extracts: hypericin or hyperforin

- antibiotics for TB (tuberculosis) or Mycobacterium complex (MAC) – rifampin and rifapentine should not be used by people taking Sunlenca

There are other drug interactions with Sunlenca.

Resistance and cross-resistance

Over time, as new copies of HIV are made in the body, the virus changes its structure. These changes, called mutations, can cause HIV to resist the effects of anti-HIV drugs, which means those drugs will no longer work for you.

To reduce the risk of developing drug resistance, all anti-HIV drugs should be taken exactly as prescribed and directed. If doses are delayed, missed or not taken as prescribed, the level of lenacapavir (and other anti-HIV medicines) in the blood may fall too low. If this happens, the HIV in your body can become resistant to the medication. If you find you are having problems taking your medications as directed, speak to your doctor, nurse or pharmacist about this. They can find ways to help you.

When HIV becomes resistant to one drug in a class, it sometimes becomes resistant to other drugs in that class. This is called cross-resistance. Feel free to talk with your doctor about your current and future treatment options. To help you decide what these future options might be, at some point your doctor can have a small sample of your blood analyzed to test for resistance.

Dosage

The dosing, formulation, schedule and administration of injectable therapy can seem complex at first. Sunlenca needs to be injected into the abdomen by a healthcare professional.

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On the 15th day after initiating Sunlenca, a healthcare provider will give you two injections of Sunlenca just under the skin of your belly.

After this, if you are on time for your next injections (in 26 weeks) and all subsequent injections, you will never need to take Sunlenca in pill form again.

While taking Sunlenca, you will also be taking other anti-HIV drugs that your doctor has prescribed.

Your doctor or clinic nurse will inject the drugs or refer you to a nurse who will do so. If a nurse will be injecting the drugs, note that your doctor will continue to provide your overall care so regular doctor visits and lab tests are important.

Speak to your nurse or doctor about your schedule of visits to get future injections. If you cannot attend your next appointment for your injections, let your doctor or nurse know right away. Gilead indicates that there is some flexibility about the timing of injections by up to two weeks. However, repeatedly missing appointments for injections may increase the risk of HIV developing resistance to Sunlenca.

Missed doses of Sunlenca pills

If you miss a dose of Sunlenca pills when initiating therapy on days 1, 2 or 8, Gilead advises that you contact your healthcare provider or pharmacist right away.

Gilead notes that if you vomit or throw up within three hours of taking Sunlenca pills, you should contact your healthcare provider right away to discuss taking another dose. However, if you vomit after three hours of taking a Sunlenca pill, Gilead advises that you do not need to take a replacement pill.

Missed Sunlenca injections

It is vital that you continue to maintain your appointments for Sunlenca injections. If you miss a planned appointment, then Sunlenca levels can fall to a low level in your body and HIV can develop the ability to resist it. Ultimately this could weaken your immune system and you could become seriously ill.

If you feel that you are not able to attend your scheduled Sunlenca injection visit, let your healthcare provider know right away. They can book you a new appointment so that you can keep taking the drug.

Changing your regimen

If you want to stop taking Sunlenca pills or injections, first speak to your doctor or nurse. They can listen to your reasons for quitting and either advise you about resolving the issues you have raised or help you find a new regimen. According to Gilead, small amounts of Sunlenca will remain in your body for up to “9 months” after you stop getting injections. It is therefore important that you adhere to your new regimen so that your viral load stays suppressed and your HIV does not become resistant to Sunlenca or other treatments.

Ogbuagu O, Segal-Maurer S, Ratanasuwan W, et al. Efficacy and safety of the novel capsid inhibitor lenacapavir to treat multidrug-resistant HIV: week 52 results of a phase 2/3 trial. *Lancet HIV*. 2023 Aug;10(8):e497-e505.

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Availability

Sunlenca is licensed in Canada as part of combination HIV treatment. It is meant for people with HIV who fit the following profile:

- aged 18 or older and
- who have used many HIV treatments in the past and
- have HIV that is resistant to many medicines and
- need to change their current HIV combination because it is not working, side effects cannot be tolerated or there are safety issues

Your doctor or pharmacist can tell you more about the availability and coverage of Sunlenca in your region. CATIE's online module *Federal, Provincial and Territorial Drug Access Programs* also contains information about Canadian drug coverage.

References

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