





Wha	t is	SUI	NLEN	ICA.
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SUNLENCA is a prescription medicine that is used with other human immunodeficiency virus-1 (HIV-1) medicines to treat HIV-1 infection in adults:

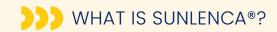
- who have received HIV-1 medicines in the past, and
- who have HIV-1 virus that is resistant to many HIV-1 medicines and
- whose current HIV-1 medicines are failing. Your HIV-1 medicines may be failing because the HIV-1 medicines are not working or no longer work, you are not able to tolerate the side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

SUNLENCA does not cure HIV-1 or AIDS. HIV-1 is the virus that causes AIDS.

IMPORTANT SAFETY INFORMATION Who should not receive or take SUNLENCA?

Do not receive or take SUNLENCA if you take other medicines called strong CYP3A inducers. Ask your healthcare provider if you are not sure.

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SUNLENCA is a long-acting injectable treatment for HIV-1 with a twice-a-year dosing schedule. SUNLENCA can help treat your HIV-1 when used in combination with the other HIV-1 medicines that have been prescribed to you by your doctor.

Adding SUNLENCA may be right for you if:

- you have received HIV-1 medicines in the past, and
- you have HIV-1 virus that is resistant to many HIV-1 medicines, and
- your 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.





IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of SUNLENCA®?

Serious side effects of SUNLENCA may include:

- Changes in your immune system. Your immune system may get stronger and begin to fight infections that may have been hidden in your body. Tell your healthcare provider if you have any new symptoms after you start taking SUNLENCA.
- Injection site reactions may happen 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.

The most common side effects of SUNLENCA were nausea and injection site reactions. These are not all the possible side effects. Tell your healthcare provider if you have any side effects that bother you or don't go away.



Between your 6-month injections, SUNLENCA keeps working in your body



SUNLENCA is a subcutaneous injection, meaning it's injected just under the skin and does not go deeply into the muscle. If you are prescribed SUNLENCA, the injections will always be given to you by a healthcare provider and may even be given at your regular appointments you may have already scheduled.



SUNLENCA is long-acting. The medicine will continue to work in your body during the 6 months between your maintenance appointments.* Make sure to attend your scheduled appointments.

*Maintenance appointments can be scheduled up to 2 weeks before or 2 weeks after the 6-month mark. If you miss a SUNLENCA appointment, contact your healthcare provider as soon as possible. They'll determine if and how you should continue with SUNLENCA, including whether temporarily switching to an oral dosage until you can resume your maintenance injections may be an option for you.





IMPORTANT SAFETY INFORMATION (cont'd)

What should I tell my healthcare provider before taking SUNLENCA®?

- All your health problems.
- All the medicines you take, including prescription and over-the-counter medicines, antacids, laxatives, vitamins, and herbal supplements, including St. John's wort. SUNLENCA and other medicines may affect each other. Keep a list of all your medicines and show it to your healthcare provider and pharmacist, and ask if it is safe to take SUNLENCA with all of your other medicines. Do not start other medicines without telling your healthcare provider. SUNLENCA may affect certain other medicines for up to 9 months after your last injection.
- If you are pregnant or plan to become pregnant. It is not known if SUNLENCA can harm your unborn baby. Tell your healthcare provider if you become pregnant while taking SUNLENCA.
- If you are breastfeeding (nursing) or plan to breastfeed. Talk to your healthcare provider about the risks of breastfeeding during treatment with SUNLENCA.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Remember, SUNLENCA works with your other HIV-1 medications. Continue to take all of your other HIV-1 medicines as prescribed by your doctor.



Take your shot with SUNLENCA

What to expect when starting treatment

There are 2 approaches to starting treatment with SUNLENCA. Your healthcare provider will discuss the options for starting SUNLENCA with you.

To start SUNLENCA, you will take SUNLENCA pills (300 mg each) in addition to receiving injections. You can take the SUNLENCA pills by mouth, with or without food. SUNLENCA pills will be delivered through a specialty pharmacy either to your home or to your provider's office. Be sure to work with your healthcare team to coordinate delivery from the specialty pharmacy.

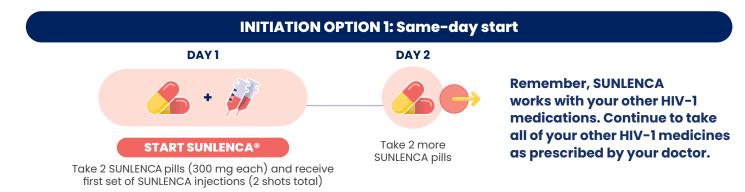
Remember, SUNLENCA works with your other HIV-1 medications. Continue to take all of your other HIV-1 medicines as prescribed by your doctor.

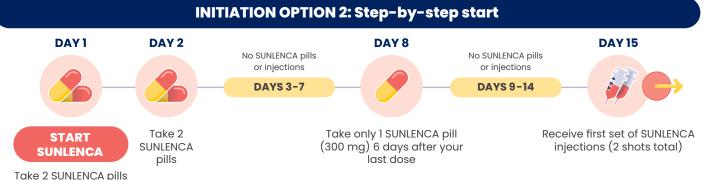


IMPORTANT SAFETY INFORMATION Who should not receive or take SUNLENCA?

Do not receive or take SUNLENCA if you take other medicines called strong CYP3A inducers. Ask your healthcare provider if you are not sure.







Remember, SUNLENCA works with your other HIV-1 medications. Continue to take all of your other HIV-1 medicines as prescribed by your doctor.

(300 mg each)





Continuing treatment with SUNLENCA

Once you've started SUNLENCA, you will get 2 injections from your healthcare provider every 6 months.* Make sure to attend your appointments as scheduled.



Remember, SUNLENCA works with your other HIV-1 medications. Continue to take all of your other HIV-1 medicines as prescribed by your doctor.

*Maintenance appointments can be scheduled up to 2 weeks before or 2 weeks after the 6-month mark. If you miss a SUNLENCA appointment, contact your healthcare provider as soon as possible. They'll determine if and how you should continue with SUNLENCA, including whether temporarily switching to an oral dosage until you can resume your maintenance injections may be an option for you.



Remember, SUNLENCA® works with your other HIV-1 medications. Continue to take all of your other HIV-1 medicines as prescribed by your doctor.

IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of SUNLENCA?

Serious side effects of SUNLENCA may include:

- Changes in your immune system. Your immune system may get stronger and begin to fight infections that may have been hidden in your body. Tell your healthcare provider if you have any new symptoms after you start taking SUNLENCA.
- Injection site reactions may happen 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.





What happens if I have to miss one of my injections?

It's important that you attend your planned appointments with your healthcare provider to receive your SUNLENCA injections. If you know that you are going to miss a scheduled 6-month injection visit by more than 2 weeks, call your healthcare provider right away to discuss your treatment options. You may have the option to take SUNLENCA tablets temporarily. This is called *oral bridging*. During this time, you will take 1 SUNLENCA 300-mg tablet once every 7 days until your injections resume. Talk to your healthcare provider about how to start oral bridging and when to resume your SUNLENCA injections.



Talk to your healthcare provider right away if you cannot attend a scheduled injection appointment. Missing SUNLENCA treatment could allow HIV to change and become harder to treat.



What should I tell my healthcare provider before starting SUNLENCA®?

Before receiving or taking SUNLENCA, tell your healthcare provider about all your medical conditions, including:

- If you are pregnant or plan to become pregnant. It is not known if SUNLENCA can harm your unborn baby. Tell your healthcare provider if you become pregnant during treatment with SUNLENCA.
- If you are breastfeeding (nursing) or plan to breastfeed. Talk to your healthcare provider about the risks of breastfeeding during treatment with SUNLENCA.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements, including St. John's wort. Some medicines may interact with SUNLENCA. Keep a list of your medicines and show it to your healthcare provider.

- You can ask your healthcare provider or pharmacist for a list of medicines that interact with SUNLENCA.
- Do not start a new medicine without telling your healthcare provider. Your healthcare provider can tell you if it is safe to take SUNLENCA with other medicines.
- SUNLENCA may affect certain other medicines for up to 9 months after your last injection.





First, it's important to understand the life cycle of HIV

Medicines that fight HIV in similar ways are grouped together in something called a *treatment class*. Most HIV treatment classes fight the virus at one step in the HIV life cycle. **To effectively fight HIV, a complete treatment regimen should include 2 or more treatment classes.**

Sometimes, HIV can develop resistance to 1 or more medicines, which means that medicine and others in that drug class may no longer work. Using different classes of HIV treatments and taking treatment as prescribed to help get to and stay undetectable helps keep HIV from developing resistance to your treatment regimen.

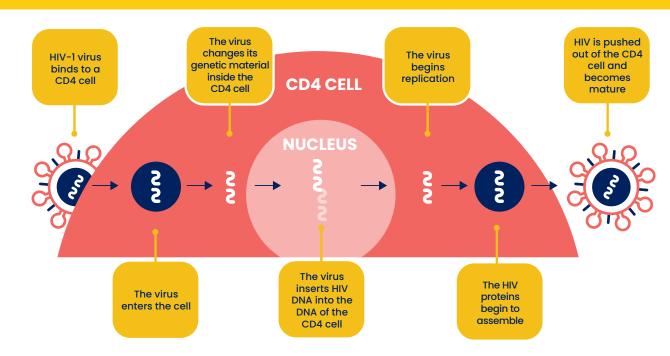
HIV-1 can develop resistance to HIV treatments. That's why sometimes they can stop working and need to be changed.



IMPORTANT SAFETY INFORMATION (cont'd) What are the possible side effects of SUNLENCA? (cont'd)

The most common side effects of SUNLENCA were nausea and injection site reactions. These are not all the possible side effects. Tell your healthcare provider if you have any side effects that bother you or don't go away.

HIV LIFE CYCLE



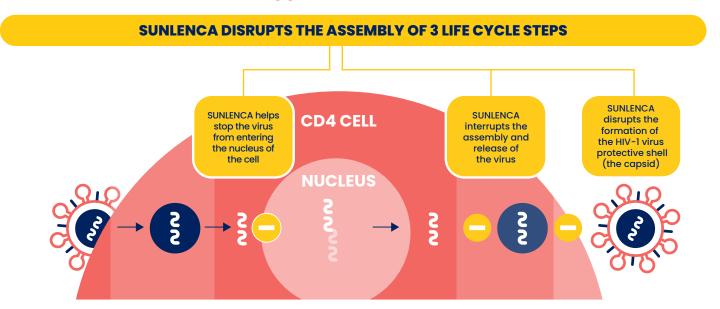
CD4 cells are an important part of the immune system that help the body fight infections.

CD4, cluster of differentiation 4.



Sunlenca® (lenacapavir) injection 463.5 mg/1.5 mL

SUNLENCA takes an innovative approach to HIV treatment



Talk to your doctor to find out if adding SUNLENCA may be your shot at getting to undetectable.



SUNLENCA® works differently and is in an HIV treatment class of its own

SUNLENCA is the first approved medicine within an entirely new HIV-1 treatment class: the *capsid inhibitor*. This means it works differently than other HIV medicines by disrupting the HIV capsid, which is important to the virus life cycle.

SUNLENCA is also the first medicine to fight HIV at 3 different steps in the virus life cycle. SUNLENCA does not treat HIV on its own. It works in combination with other HIV medications. People receiving SUNLENCA injections or tablets will continue to take their other HIV-1 medications as prescribed.

Adding SUNLENCA to your other HIV medicines may be your shot to help lower the amount of HIV virus in your blood.

IMPORTANT SAFETY INFORMATION (cont'd)

What should I tell my healthcare provider before taking SUNLENCA?

- All your health problems.
- All the medicines you take, including prescription and over-the-counter medicines, antacids, laxatives, vitamins, and herbal supplements, including St. John's wort. SUNLENCA and other medicines may affect each other. Keep a list of all your medicines and show it to your healthcare provider and pharmacist, and ask if it is safe to take SUNLENCA with all of your other medicines. Do not start other medicines without telling your healthcare provider. SUNLENCA may affect certain other medicines for up to 9 months after your last injection.



Sunlenca (lenacapavir) injection 463.5 mg/1.5 mL

See how SUNLENCA worked in a clinical study

SUNLENCA was studied in adults with HIV that was resistant to other HIV medications

A study was conducted to find out if adding SUNLENCA to other HIV medications helped people significantly decrease the amount of HIV virus in their blood in 2 weeks (15 days) and reach and stay undetectable (less than 50 copies/mL of the HIV virus in the blood) after 6 months (26 weeks) and 12 months (52 weeks) of treatment.

IMPORTANT SAFETY INFORMATION (cont'd)

What should I tell my healthcare provider before taking SUNLENCA? (cont'd)

- If you are pregnant or plan to become pregnant. It is not known if SUNLENCA can harm your unborn baby. Tell your healthcare provider if you become pregnant while taking SUNLENCA.
- **If you are breastfeeding** (nursing) or plan to breastfeed. Talk to your healthcare provider about the risks of breastfeeding during treatment with SUNLENCA.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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with detectable levels of HIV-1 that was resistant to other HIV-1 medicines. The adults chosen for the study had a limited amount of remaining treatment options to try.

Participants chosen had:

- A viral load of ≥400 copies/mL
- Resistance to at least 2 medications from each of at least 3 different HIV treatment classes
- Two or fewer HIV-1 medications available to them without resistance, intolerability, drug access, or other safety concerns

†People who started with a placebo took SUNLENCA tablets in addition to their other HIV-1 medicines for 2 weeks before starting SUNLENCA injections. †During the trial, many participants also took oral SUNLENCA temporarily (one 300-mg tablet once every 7 days) when they couldn't receive their every-6-month injection on time.

START OF STUDY



Group 1 36 adults

Some adults in Group 1 added SUNLENCA® right away. Others added a placebo for 2 weeks before swapping the placebo for SUNLENCA. After 2 weeks, participants were receiving SUNLENCA injections in addition to taking their other HIV-1 medicines as prescribed by their doctors.[†]

12 adults started with a PLACEBO

Some of the adults in Group 1 were given placebo tablets in addition to their other HIV-1 medicines.

24 adults added SUNLENCA

Some of the adults in Group 1 were given SUNLENCA tablets right away in addition to their other HIV-1 medicines.

2 WEEKS (15 DAYS)

After 2 weeks, participants were receiving SUNLENCA injections every 6 months in addition to their other medicines.†



6 MONTHS/1 YEAR (26 WEEKS/52 WEEKS)

Participants received SUNLENCA injections every 6 months in addition to their other HIV-1 medicines.‡





SUNLENCA helped to quickly decrease the viral load in most people after just 2 weeks

In Group 1, 88% of adults (21 of 24 people) had less HIV virus in their blood after adding SUNLENCA and continuing to take the other HIV medicines that were prescribed by their healthcare providers.



88%

of adults had less HIV virus in their blood 15 days after adding SUNLENCA, as compared to 17% (2 of 12) of adults on placebo.

IMPORTANT SAFETY INFORMATION

Who should not receive or take SUNLENCA®?

Do not receive or take SUNLENCA if you take other medicines called strong CYP3A inducers. Ask your healthcare provider if you are not sure.

What were the side effects with SUNLENCA?

The most common side effects seen with SUNLENCA, experienced in at least 3% of the people in the clinical study through Week 52 (1 year), were nausea (4%) and injection site reactions (65%). The majority (96%) of the side effects associated with SUNLENCA were mild or moderate in severity.

• Through 1 year of the clinical trial, 1 person stopped taking SUNLENCA due to an injection site reaction. No other participants stopped taking SUNLENCA due to side effects through 1 year.

These are not the only possible side effects of SUNLENCA. Tell your healthcare provider if you have any side effects that bother you or do not go away.



SUNLENCA helped adults reach undetectable, and most adults remained undetectable after I year

In Group 1, 81% of adults (29 of 36 people) who added SUNLENCA and continued to take the other HIV medicines that were prescribed by their healthcare provider reached undetectable (less than 50 copies/mL of the HIV virus in the blood) by the 6-month mark. After a year, 83% of adults (30 of 36 people) were still undetectable.



SUNLENCA may be your shot to help you reach undetectable. Ask your healthcare provider about adding SUNLENCA.





Who should not take SUNLENCA®?

Do not receive or take SUNLENCA if you also take certain medicines called *CYP3A* inducers. Ask your healthcare provider if you are not sure whether this applies to any medications you are taking.

What were the side effects with SUNLENCA?

The most common side effects seen with SUNLENCA, experienced in at least 3% of the people in the clinical study through 1 year, were **nausea** (4%) and **injection site reactions** (65%).

96% of side effects reported in the study that were associated with SUNLENCA were **mild or moderate** in severity.

 Through 1 year of the clinical trial, 1 person stopped taking SUNLENCA due to an injection site reaction. No other participants stopped taking SUNLENCA due to side effects through 1 year.

These are not the only possible side effects of SUNLENCA. Tell your healthcare provider if you have any side effects that bother you or do not go away.





SUNLENCA® may also cause serious side effects, including:

- Changes in your immune system. Your immune system may get stronger and begin to fight infections that may have been hidden in your body. Tell your healthcare provider if you have any new symptoms after you start taking SUNLENCA.
- Injection site reactions may happen 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.



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SUNLENCA® SUPPORT RESOURCES

If your healthcare provider has already determined that a Gilead treatment is right for you

The Gilead Advancing Access® program is committed to helping you afford your medication, no matter your situation.

Whether you are insured or uninsured, Advancing Access may be able to help in the following ways:



If you are eligible, Advancing Access may be able to help you lower your co-pay to as little as \$0.8



Identify potential sources of financial support if you have government insurance or are uninsured.



For more information, visit

<u>GileadAdvancingAccess.com</u> or call 1-800-226-2056, Monday-Friday, 9 AM to 8 PM ET.

§Eligible, commercially insured individuals enrolled in the Gilead Advancing Access co-pay coupon card program could pay as little as \$0. Uninsured individuals can contact Gilead's Advancing Access program for information about support options. Restrictions apply. Subject to change. See full terms and conditions at GileadAdvancingAccess.com.





IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of SUNLENCA®? (cont'd)

• Injection site reactions may happen 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.

The most common side effects of SUNLENCA were nausea and injection site reactions. These are not all the possible side effects. Tell your healthcare provider if you have any side effects that bother you or don't go away.

What should I tell my healthcare provider before taking SUNLENCA?

· All your health problems.

Share your story. Inspire others. Become an advocate. If interested, please call us at 1-888-235-7070 or send us an email at info@GANteam.com to get started.



SUNLENCA® may be your shot to take on hard-to-treat HIV

IMPORTANT SAFETY INFORMATION (cont'd)

What should I tell my healthcare provider before taking SUNLENCA? (cont'd)

• All the medicines you take, including prescription and over-the-counter medicines, antacids, laxatives, vitamins, and herbal supplements, including St. John's wort. SUNLENCA and other medicines may affect each other. Keep a list of all your medicines and show it to your healthcare provider and pharmacist, and ask if it is safe to take SUNLENCA with all of your other medicines. Do not start other medicines without telling your healthcare provider. SUNLENCA may affect certain other medicines for up to 9 months after your last injection.

Please click for Important Facts about <u>SUNLENCA</u>, including who should not take SUNLENCA.







Start the conversation with your healthcare provider about whether SUNLENCA may be an option for you

Interested in learning more? Visit <u>SUNLENCA.com</u>.



(sun-LEN-kuh)

IMPORTANT FACTS

This is only a brief summary of important information about SUNLENCA® and does not replace talking to your healthcare provider about your condition and your treatment.

ABOUT SUNLENCA

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.

SUNLENCA does not cure HIV-1 or AIDS. HIV-1 is the virus that causes AIDS.

Do NOT receive or take SUNLENCA if you also take certain other medicines called strong CYP3A inducers. Ask your healthcare provider if you are not sure.

BEFORE RECEIVING OR TAKING SUNLENCA

Tell your healthcare provider all your medical conditions, including if you:

- Are pregnant or plan to become pregnant.
- Are breastfeeding (nursing) or plan to breastfeed.
 Talk to your healthcare provider about the risks of breastfeeding during treatment with SUNLENCA.

Tell your healthcare provider about all the medicines you take:

- Keep a list that includes all prescription and over-the-counter medicines, vitamins, and herbal supplements, including St. John's wort, and show it to your healthcare provider and pharmacist.
- Ask your healthcare provider or pharmacist about medicines that interact with SUNLENCA.
- SUNLENCA may affect certain other medicines for up to 9 months after your last injection.

POSSIBLE SIDE EFFECTS OF SUNLENCA

SUNLENCA can cause serious side effects, including:

- · Changes in your immune system.
- Injection site reactions, including 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. Tell your healthcare provider if you have any injection site reactions.
- The most common side effects of SUNLENCA are nausea and injection site reactions.

These are not all the possible side effects of SUNLENCA. Tell your healthcare provider right away if you have any new symptoms while taking SUNLENCA.

HOW TO RECEIVE AND TAKE SUNLENCA

SUNLENCA treatment will consist of injections and tablets. SUNLENCA injections will be given to you by your healthcare provider under the skin (subcutaneous injection) in your stomach-area (abdomen). Take SUNLENCA tablets by mouth, with or without food.

There are two options (Option 1 and Option 2) to start treatment with SUNLENCA. Your healthcare provider will decide which starting option is for you.

- If Option 1 is chosen:
 - On Day 1, you will receive 2 SUNLENCA injections and take 2 SUNLENCA tablets.
 - On Day 2, you will take 2 SUNLENCA tablets.
- If Option 2 is chosen:
 - On Day 1 and Day 2, you will take 2 SUNLENCA tablets each day.
 - On Day 8, you will take 1 SUNLENCA tablet.
 - On Day 15, you will receive 2 SUNLENCA injections.

After completing Option 1 or Option 2, you will receive 2 SUNLENCA injections every 6 months (26 weeks) from the date of your last injection. If you miss or plan to miss your scheduled every 6 month injection of SUNLENCA, call your healthcare provider right away to discuss your treatment options.

GET MORE INFORMATION

- This is only a brief summary of important information about SUNLENCA. Talk to your healthcare provider or pharmacist to learn more.
- Go to SUNLENCA.com or call 1-800-GILEAD-5.
- If you need help paying for your medicine, visit SUNLENCA.com for program information.

