

<p style="text-align: center;">SUNLENCA® (sun-LEN-kuh) (lenacapavir) tablets</p>	<p>Patient Information</p>	<p style="text-align: center;">SUNLENCA® (sun-LEN-kuh) (lenacapavir) injection</p>
<p>What is SUNLENCA?</p> <p>SUNLENCA is a prescription medicine that is used with other human immunodeficiency virus-1 (HIV-1) medicines to treat HIV-1 infection in adults:</p> <ul style="list-style-type: none"> • 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. <p>HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS). It is not known if SUNLENCA is safe and effective in children.</p>		
<p>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.</p>		
<p>Before receiving or taking SUNLENCA, tell your healthcare provider about all your medical conditions, including if you:</p> <ul style="list-style-type: none"> • 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. Pregnancy Registry: There is a pregnancy registry for women who take SUNLENCA during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk with your healthcare provider about how you can take part in this registry. • are breastfeeding or plan to breastfeed. Do not breastfeed if you take SUNLENCA. <ul style="list-style-type: none"> ○ You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby. ○ It is not known if SUNLENCA can pass to your baby in your breast milk. ○ Talk with your healthcare provider about the best way to feed your baby during treatment with SUNLENCA. <p>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.</p> <p>Some medicines may interact with SUNLENCA. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.</p> <ul style="list-style-type: none"> • 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. 		
<p>How should I receive and take SUNLENCA?</p> <ul style="list-style-type: none"> • Your SUNLENCA treatment will consist of injections and tablets. <ul style="list-style-type: none"> ○ 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. <ul style="list-style-type: none"> ○ If Option 1 is chosen: <ul style="list-style-type: none"> ▪ 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: <ul style="list-style-type: none"> ▪ 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. • Stay under the care of a healthcare provider during treatment with SUNLENCA. It is important that you attend your planned appointments to receive your injections of SUNLENCA. • If you miss your scheduled injection appointment, call your healthcare provider right away to discuss your treatment 		

options. Missing an injection of SUNLENCA may cause the HIV-1 virus to change (mutate) and become harder to treat (resistant).

- Tell your healthcare provider right away if you stop receiving SUNLENCA or stop taking any other antiretroviral medicines. If you stop treatment with SUNLENCA you will need other medicines to treat your HIV-1 infection. If you do not take other HIV-1 medicines, the amount of virus in your blood may increase and the virus may become harder to treat. Call your healthcare provider right away to discuss your treatment options.
- If you take too many SUNLENCA tablets, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of SUNLENCA?

SUNLENCA may cause serious side effects, including:

- **Changes in your immune system (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 start having 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.

The most common side effects of SUNLENCA are nausea and injection site reactions.

These are not all of the possible side effects of SUNLENCA.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store SUNLENCA tablets?

- Store SUNLENCA tablets at room temperature between 68 °F to 77 °F (20 °C to 25 °C).
- Keep SUNLENCA tablets in their original blister pack.

Keep SUNLENCA and all medicines out of reach of children.

General information about the safe and effective use of SUNLENCA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use SUNLENCA for a condition for which it was not prescribed. Do not give SUNLENCA to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about SUNLENCA that is written for health professionals.

What are the ingredients in SUNLENCA?

Active ingredient: lenacapavir

Inactive ingredients:

SUNLENCA tablets: copovidone, croscarmellose sodium, magnesium stearate, mannitol, microcrystalline cellulose, and poloxamer 407. The tablets are film-coated with a coating material containing iron oxide black, iron oxide red, iron oxide yellow, polyethylene glycol, polyvinyl alcohol, talc, and titanium dioxide.

SUNLENCA injection: polyethylene glycol 300 and water for injection.

Manufactured and distributed by: Gilead Sciences, Inc. Foster City, CA 94404

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For more information, call 1-800-445-3235 or go to www.SUNLENCA.com.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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