

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

### 1. Why am I using SUNLENCA?

SUNLENCA contains the active ingredient lenacapavir. SUNLENCA is used to treat adults who have HIV-1 that are resistant to many other antiretroviral medicines. SUNLENCA is prescribed in combination with other antiretroviral medicines. It is used to treat HIV infection in adults with limited treatment options (for example when other antiretroviral medicines are not sufficiently effective or are not suitable).

For more information, see Section [1. Why am I using SUNLENCA?](#) in the full CMI.

### 2. What should I know before I use SUNLENCA?

Do not use if you have ever had an allergic reaction to SUNLENCA or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use SUNLENCA?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with SUNLENCA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use SUNLENCA?

- Your treatment with SUNLENCA starts with tablets taken on Days 1, 2, and 8 followed by two injections on Day 15, and then continues with two injections every six months.
- Talk to your doctor before taking SUNLENCA tablets.

More instructions can be found in Section [4. How do I use SUNLENCA?](#) in the full CMI.

### 5. What should I know while using SUNLENCA?

Things you should do	<ul style="list-style-type: none"><li>Remind any doctor, dentist or pharmacist you visit that you are using SUNLENCA.</li><li>Attend your planned appointments every 6 months to receive your SUNLENCA injection.</li><li>Continue to take your other antiretroviral medications as directed.</li></ul>
Things you should not do	<ul style="list-style-type: none"><li>Do not stop receiving SUNLENCA without talking to your doctor.</li></ul>
Looking after your medicine	<ul style="list-style-type: none"><li>Store in the original package.</li><li>Store below 30 °C.</li><li>SUNLENCA injection is sensitive to light.</li></ul>

For more information, see Section [5. What should I know while using SUNLENCA?](#) in the full CMI.

### 6. Are there any side effects?

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

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

# SUNLENCA

Active ingredient: *lenacapavir*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using SUNLENCA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using SUNLENCA.**

Where to find information in this leaflet:

- [1. Why am I using SUNLENCA?](#)
- [2. What should I know before I use SUNLENCA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use SUNLENCA?](#)
- [5. What should I know while using SUNLENCA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using SUNLENCA?

**SUNLENCA contains the active ingredient lenacapavir.** SUNLENCA injection is a long acting medicine and is used in combination with SUNLENCA tablets and with other antiretroviral medicines to treat type 1 human immunodeficiency virus (HIV-1).

**SUNLENCA** is used to treat adults who have HIV-1 infection with limited treatment options (for example when other antiretroviral medicines are not sufficiently effective or are not suitable).

SUNLENCA reduces the amount of HIV in your body. This will improve the immune system and reduce the risk of developing illnesses linked to HIV infection.

## 2. What should I know before I use SUNLENCA?

### Warnings

**Do not use SUNLENCA if:**

- you are allergic to lenacapavir, or any of the ingredients listed at the end of this leaflet.
- always check the ingredients to make sure you can use this medicine.
- you are currently taking rifampicin used to treat some bacterial infections such as tuberculosis.

**Check with your doctor if you:**

- have any other medical conditions
- take any medicines for any other condition

- have or have had severe liver disease, or if tests have shown problems with your liver.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known if the active substance in this medicine passes into human breast milk. Talk with your doctor about the best way to feed your baby.

## Does SUNLENCA reduce the risk of passing HIV to others?

You can still pass on HIV when taking this medicine, although the risk is lowered by effective antiretroviral therapy. Discuss with your doctor the precautions you need to take to avoid infecting other people. This medicine is not a cure for HIV infection. While taking SUNLENCA you may still develop infections or other illnesses associated with HIV infection.

## 3. What if I am taking other medicines?

Tell your doctor or pharmacist about any other medicines you are taking, including vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

SUNLENCA may interact with other medicines. As a result, the amounts of SUNLENCA or other medicines in your blood may change. This may stop your medicines working properly, or may make side effects worse. In some cases, your doctor may need to adjust your dose or check your blood levels.

**Medicines that must never be taken with SUNLENCA:**

- rifampicin
- carbamazepine or phenytoin
- St. John's Wort or products containing St John's Wort

**Talk to your doctor if you are taking:**

- atazanavir/cobicistat, efavirenz, nevirapine or tripranavir/ritonavir
- oxcarbazepine or phenobarbital
- dexamethasone or hydrocortisone/cortisone
- digoxin
- dihydroergotamine or ergotamine
- lovastatin or simvastatin
- midazolam or triazolam
- rifabutin
- rivaroxaban or dabigatran
- tadalafil, sildenafil or vardenafil

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect SUNLENCA.**

## 4. How do I use SUNLENCA?

SUNLENCA is used in combination with other antiretroviral medicines to treat HIV-1 infection. Your doctor will advise which other medicines you need to take to treat your HIV-1 infection, and when you need to take them.

Your treatment with SUNLENCA starts with tablets taken on Day 1, Day 2 and Day 8 followed by two injections on Day 15, and then continues with two injections every six months.

**Day 1 of treatment:**

- Two (300 mg) tablets taken by mouth. These can be taken with or without food. Talk to your doctor before taking the tablets

**Day 2 of treatment:**

- Two (300 mg) tablets taken by mouth. These can be taken with or without food.

**Day 8 of treatment:**

- One (300mg) tablet taken by mouth. This can be taken with or without food.

**Day 15 of treatment:**

- Two injections into your abdomen given by your doctor or nurse.

**Every 6 months:**

- Two injections into your abdomen (tummy) given by your doctor or nurse.

**If you forget a SUNLENCA tablet**

- It is important not to miss a dose of SUNLENCA tablets.
- If you forget to take your tablets on Day 1, Day 2 or on Day 8, contact your doctor or pharmacist immediately.
- If you vomit within 3 hours after taking SUNLENCA tablets, contact your doctor immediately. If you vomit more than 3 hours after taking SUNLENCA you do not need to take more tablets.

**If you miss a SUNLENCA injection**

- It is important that you attend your planned appointments every 6 months to receive your injections of SUNLENCA. This will help to control your HIV infection and to stop your illness getting worse.
- If you think you will not be able to attend your injections appointment, call your doctor as soon as possible to discuss your treatment options.

**Do not stop receiving SUNLENCA** without talking to your doctor. Keep receiving SUNLENCA injections for as long as your doctor recommends. Stopping SUNLENCA can seriously affect how future treatment works.

**SUNLENCA injection is a long-acting medicine.** If after talking to your doctor you decide to stop your treatment, you should know low levels of lenacapavir (the active ingredient in SUNLENCA) can remain in your system for many months after your last injection. Other antiretroviral medicines that you take to treat your HIV-1 infection should not be affected by the low levels of lenacapavir. Some other medicines however may be affected by the low levels of lenacapavir in your system if you take them within 9 months after your last SUNLENCA injection. You should check with your doctor which other medicines are safe for you to take when you stop treatment with lenacapavir.

**Talk to your doctor if you want to stop receiving SUNLENCA injections.**

**If you are given too much SUNLENCA injection**

Your doctor or a nurse will give this medicine to you, so it is unlikely that you will be given too much. If you are worried, tell the doctor or a nurse.

## 5. What should I know while using SUNLENCA?

### Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using SUNLENCA.
- Attend your planned appointments every 6 months to receive your SUNLENCA injection to control your HIV infection, and to stop your illness from getting worse.

### Things you should not do

- Do not stop receiving SUNLENCA without talking to your doctor.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how SUNLENCA affects you.**

SUNLENCA is not expected to have any effect on your ability to drive or use machines.

### Looking after your medicine

**Keep this medicine out of the sight and reach of children.**

#### Injection:

- Store in the original package. Store below 30 °C.
- Sensitive to light.

#### Tablets:

- Store in the original package. Store below 30 °C.

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"><li>• Reactions where SUNLENCA is injected, such as:<ul style="list-style-type: none"><li>- Pain and discomfort</li><li>- A hardened mass or lump</li><li>- Inflammatory reaction such as redness, itching and swelling</li></ul></li><li>• Nausea</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>• <b>Any signs of inflammation or infection</b> In some patients with advanced HIV infection (AIDS) and a history of opportunistic infections (infections that occur in people with a weak immune system), signs and symptoms of inflammation from previous infections may occur soon after HIV treatment is started. It is thought that these symptoms are due to an improvement in the body's immune response, enabling the body to fight infections that may have been present with no obvious symptoms.</li></ul>	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. PRODUCT DETAILS

This medicine is only available with a doctor's prescription.

### What SUNLENCA contains

<b>Active ingredient (main ingredient)</b>	lenacapavir
<b>Other ingredients (inactive ingredients)</b>	<b>Injection:</b> macrogol 300 water for injection  <b>Tablets:</b> Tablet core: mannitol microcrystalline cellulose croscarmellose sodium copovidone magnesium stearate poloxamer 407  <b>Film coating:</b> polyvinyl alcohol titanium dioxide macrogol 3350 purified talc iron oxide yellow iron oxide black iron oxide red
<b>Potential allergens</b>	N/A

**Do not take this medicine if you are allergic to any of these ingredients.**

### What SUNLENCA looks like

SUNLENCA solution for injections are clear, yellow to brown solution with no visible particles. SUNLENCA comes in two glass vials. These vials are included in a dosing kit also containing 2 vial access devices (a device that will allow your doctor or a nurse to withdraw SUNLENCA from the vial), 2 disposable syringes and 2 injection needles.

SUNLENCA film-coated tablets are beige, capsule-shaped, film-coated tablets, debossed with "GSI" on one side of the tablet and "62L" on the other side of the tablet. SUNLENCA comes in a blister of 5 tablets surrounded by a blister card. The blister is placed within a foil pouch. The foil pouch contains a silica gel desiccant that must be kept in the foil pouch to help protect your tablets. The silica gel is contained in a separate sachet or canister and is not to be swallowed.

SUNLENCA 463.5 mg/1.5 mL solution for injection vial:  
AUST R 386895

SUNLENCA 300 mg tablet:  
AUST R 392350

### Who distributes SUNLENCA

Gilead Sciences Pty Ltd  
Level 6, 417 St Kilda Road  
Melbourne, Victoria 3004  
Australia

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