Patient leaflet in accordance with the Pharmacists' (Products) Regulations - 1986

This medicine is to be supplied by doctor's prescription only

Sunlenca® film-coated tablets

lenacapavir

Active ingredients: Each tablet contains –

lenacapavir (as sodium)	300 mg

Inactive and allergenic substances: see section 6 *"Additional information*".

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. This leaflet contains essential information about this medicine. If you have any further questions, ask your doctor or pharmacist. Keep this leaflet. You may need to read it again. This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours. If you experience any side effects, talk to your doctor or pharmacist. Even if you experience any side effects that are not listed in this leaflet (see section 4).

This medicine is intended for adults aged 18 years and over.

1. What is the medicine intended for

Sunlenca film-coated tablet, in combination with other antiretroviral(s), is indicated for the treatment of adults with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive anti-viral regimen, for oral loading prior to administration of long-acting lenacapavir injection.

Therapeutic group: Antivirals for systemic use, other antivirals.

Sunlenca **is used in combination with other antiretroviral medicines** to treat type 1 human immunodeficiency virus (HIV), the virus that cause acquired immunodeficiency syndrome (AIDS).

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).

Treatment with Sunlenca in combination with other antiretrovirals reduces the amount of HIV in your body. This will improve the function of your immune system (the body's natural defences) and reduce the risk of developing illnesses linked to HIV infection.

Your doctor will advise you to take Sunlenca tablets before you are given Sunlenca injections for the first time.

Sunlenca contains the active substance **lenacapavir**. This is an antiretroviral medicine known as a capsid inhibitor.

2. Before taking the medicine

X Do not take this medicine

- **If you are allergic to lenacapavir** or any of the other ingredients of the medicine (listed in section 6 of this leaflet).

- If you are taking any of these medicines:
  - **rifampicin**, used to treat some bacterial infections such as tuberculosis
  - **carbamazepine**, **phenytoin**, used to prevent seizures
  - **St. John's wort** (*Hypericum perforatum*), a herbal remedy used for depression and anxiety

→ **Do not take Sunlenca and tell your doctor immediately** if you think this applies to you**.**

! Special warnings relating to the use of the medicine

Talk to your doctor before taking Sunlenca

- **Talk to your doctor or pharmacist if you have ever had severe liver disease, or if tests have shown problems with your liver.** Your doctor will carefully consider whether to treat you with Sunlenca.

While you are using Sunlenca

Once you start using Sunlenca, look out for:

- **Signs of inflammation** or **infection**.

→ **If you notice any of these symptoms, tell your doctor immediately.** For more information, see section 4, *Side effects*.

Children and adolescents

Do not give this medicine to children under 18 years of age. **There is no information** about use of Sunlenca in patients aged under 18.

Drug-Drug Interactions

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including non-prescription medicines and dietary supplements. Sunlenca may interact with other medicines. This may keep Sunlenca or other medicines from 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** used to treat some bacterial infections, such as tuberculosis
- **carbamazepine, phenytoin**, used to prevent seizures
- **St. John's wort (*Hypericum perforatum*)**, a herbal remedy used for depression and anxiety

→ If you are taking any of these medicines, **do not take Sunlenca tablets and tell your doctor immediately**.

Talk to your doctor in particular if you are taking:

- antibiotics containing:

  - rifabutin
- anticonvulsants used to treat epilepsy and prevent seizures (fits), containing:
  - oxcarbazepine or phenobarbital
- medicines used to treat HIV, containing:
  - atazanavir/cobicistat, efavirenz, nevirapine, tipranavir/ritonavir or etravirine
- medicines used to treat migraine headache, containing:
  - dihydroergotamine or ergotamine
- medicine used to treat impotence and pulmonary hypertension, containing:
  - sildenafil or tadalafil
- medicine used to treat impotence, containing:
  - vardenafil
- corticosteroids (also known as 'steroids') taken orally or given by injection used to treat allergies, inflammatory bowel diseases, and other various illnesses involving inflammations in your body, containing:
  - dexamethasone or hydrocortisone/cortisone
- medicines used to lower cholesterol, containing:
  - lovastatin or simvastatin
- antiarrhythmics used to treat heart problems, containing:
  - digoxin
- medicines used to help you sleep, containing:
  - midazolam or triazolam.
- anticoagulants used to prevent and treat blood clots, containing:
  - rivaroxaban, dabigatran or edoxaban

→ **Tell your doctor if you are taking any of these medicines** or if you start taking any of these medicines during treatment with Sunlenca. Do not stop any treatment without contacting your doctor.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

The use of Sunlenca in pregnant women is limited, therefore you should avoid the use of Sunlenca during pregnancy unless your doctor tells you otherwise.

Breast-feeding is not recommended in women who are HIV-positive because HIV virus can be passed on to the baby through breast milk. It is unknown whether lenacapavir is excreted in breast milk, therefore if you are breast-feeding, or thinking about breast-feeding, **you should discuss it with your doctor as soon as possible.**

Driving and using machines

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

Important information about some ingredients of the medicine

Sunlenca contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take the medicine

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure regarding the dose and treatment regimen.

The dose and treatment regimen will be determined by a doctor.

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

Your treatment with Sunlenca starts with tablets you take by mouth, followed by injections given by your doctor or nurse, as described below.

Talk to your doctor before taking the tablets. You will be advised when to start your tablets and when your appointment for the first injections will be scheduled.

Day 1 of treatment:
- Two tablets taken by mouth. These can be taken with or without food

Day 2 of treatment:
- Two tablets taken by mouth. These can be taken with or without food.

Day 8 of treatment:
- One tablet taken by mouth. These can be taken with or without food.

Day 15 of treatment:
- Two injections into your abdomen (tummy) given at the same time by your doctor or nurse.

Every 6 months:
- Two injections into your abdomen given at the same time by your doctor or nurse.

No information available regarding tablet effectiveness after splitting, chewing or crushing it.

Do not exceed the recommended dose.

If you take more Sunlenca than you should

Contact your doctor or pharmacist immediately for advice. If you take more than the recommended dose of Sunlenca, you may be at higher risk of side effects (see section 4, *Side effects*).
If you take more than you should or if a child has accidentally swallowed some of the medicine, contact your doctor or nearest hospital emergency department immediately and bring the tablet carton with you.

If you forget to take Sunlenca

It is important not to miss a dose of Sunlenca tablets.

If you forget to take your tablets, contact your doctor or pharmacist immediately.

If you vomit within 3 hours after taking Sunlenca tablets, contact your doctor immediately and take another two tablets. If you vomit more than 3 hours after taking Sunlenca you do not need to take more tablets until your next scheduled tablets or injection.

You should adhere to the treatment as recommended by your doctor.

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.
- If you think you will not be able to attend your appointment for your injections, call your doctor as soon as possible to discuss your treatment options.

Do not stop taking Sunlenca

Do not stop taking Sunlenca tablets without talking to your doctor. Stopping Sunlenca can seriously affect how future treatments against HIV infection will work.

Do not take medicines in the dark!
Check the label and the dose each time you take a medicine.
Wear glasses if you need them.

If you have any further questions on the use of this medicine, consult your doctor or pharmacist.

4. Side effects

Like all medicines, Sunlenca can cause side effects for some users.
Do not be alarmed by reading the list of side effects. You may not experience any of them.

Possible serious side effects: tell a doctor immediately

- **Any signs of inflammation or infection.** 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.

- **Autoimmune disorders**, when the immune system attacks healthy body tissue, may also occur after you start taking medicines for HIV infection. Autoimmune disorders may occur many months after the start of treatment. Look out for any symptoms of infection or other symptoms such as:
  - muscle weakness
  - weakness beginning in the hands and feet and moving up towards the trunk of the body
  - palpitations, tremor or hyperactivity

→ If you notice these or any symptoms of inflammation or infection, **tell your doctor immediately.**

Common side effects
(affect 1-10 out of 100 users)
- **Feeling sick** (nausea)

→ If a side effect has appeared, if any of the side effects worsen or if you suffer from a side effect not mentioned in the leaflet, consult the doctor.

Reporting of side effects
You can report any side effects to the Ministry of Health by clicking on the link "Report side effects due to medical treatment" that is located on the Ministry of Health homepage (www.health.gov.il) which redirects to the online form for reporting side effects or by clicking on the link: https://sideeffects.health.gov.il .

You can also report any side effects directly to the registration holder via email: DrugSafety.Israel@gilead.com.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store the medicine

Prevent poisoning! Keep this medicine out of the sight and reach of children and/or babies to prevent poisoning. Do not induce vomiting without a doctor's express instruction.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions. Recommended to store at room temperature. Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

What Sunlenca contains

The active substance is lenacapavir. Each tablet contains lenacapavir sodium equivalent to 300 mg lenacapavir.

In addition to the active ingredient/s, the medicine also contains:

Tablet core
Mannitol (E421), microcrystalline cellulose (E460), croscarmellose sodium (E468), copovidone, magnesium stearate (E572), poloxamer (see section 2, *Sunlenca contains sodium*).

Film-coating
Polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol (E1521), talc (E553b), iron oxide yellow (E172), iron oxide black (E172), iron oxide red (E172).

What the medicine looks like and contents of the pack

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.

Manufacturer
Gilead Sciences Ireland UC
IDA Business & Technology Park
Carrigtohill
County Cork
Ireland

Registration Holder
Gilead Sciences Israel Ltd.
4 HaHarash Street
Hod Hasharon 4524075
Israel

The medicine's registration no. in the national register of medicines at the Ministry of Health:

34740

For simplicity and ease of reading, this leaflet was phrased in the masculine. Nevertheless, the medicine is intended for both sexes.

This leaflet has been checked and approved by Ministry of Health in July 2023.

Reference: EU SmPC Oct 2022

IL-JUL23-EU-OCT22