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

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

Sunlenca® solution for injection

lenacapavir 463.5 mg/vial

Active ingredients: Each ml contains –

lenacapavir (as sodium)	309 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 solution for injection, 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.

Therapeutic group: Antivirals for systemic use, other antivirals.

Sunlenca is a long acting medicine and **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.

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 receive 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 using 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*.

- **Reactions where Sunlenca is injected.**

→ A hardened mass or lump may occur at the injection site. In some cases, such lumps have remained for more than a year and in some cases may not go away. If this has not gone away at the time of the next injection, alert your doctor. For more information, see section 4, S*ide effects*.

Regular appointments are important

It is important that you **attend your planned appointments** to receive your Sunlenca injection, to control your HIV infection, and to stop your illness from getting worse. Talk to your doctor if you are thinking about stopping treatment. If you are late receiving your Sunlenca injection, or if you stop receiving Sunlenca, your will need to take other medicines to treat your HIV infection and to reduce the risk of developing viral resistance.

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. This includes 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 receive Sunlenca injection 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.

Sunlenca is a long-acting medicine. If after talking to your doctor you decide to stop your treatment or switch to another, you should know low levels of lenacapavir (the active substance in Sunlenca) can remain in your system for many months after your last injection. These low remaining levels should not affect other antiretroviral medicines that you take afterwards to treat your HIV infection. 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 if such medicines are safe for you to take after you stop treatment with Sunlenca.

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 living with HIV 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 injection, 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. This 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.

Do not exceed the recommended dose.

If you are given more Sunlenca injection than you should

The therapy is provided by your doctor or nurse. If there is a concern of receiving a dose higher than required, tell the doctor or a nurse.

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 from getting worse.
- 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.

If you miss or vomit the tablets, refer to the package leaflet for Sunlenca tablets.

Do not stop taking Sunlenca

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 HIV treatments work.

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

Do not take medicines in the dark!
Check the label and the dose <u>every time</u> 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.**

Very common side effects
(may affect more than 1 in 10 users)
- **Reactions where Sunlenca is injected.**
  Symptoms may include:
  - pain and discomfort

- a hardened mass or lump which may take longer to go away than other reactions at the injection site or may not go away
- inflammatory reaction such as redness, itching, and swelling
- open sore on the skin

Common side effects
(may affect up to 1-10 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 .

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

5. How to store Sunlenca

Prevent poisoning! Keep this medicine out of the sight and reach of children and/or babies. In this way you will prevent poisoning.

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

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

6. Additional information

What Sunlenca solution for injection contains

The active substance is lenacapavir. Each single-use vial contains 463.5 mg of lenacapavir.

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

Macrogol (E1521), water for injections.

What the medicine looks like and contents of the pack

Sunlenca solution for injection (injection) is a clear, yellow to brown solution with no visible particles. Sunlenca comes in two glass vials, each containing 1.5 ml of solution for injection. 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.

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:
34743

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