

Package leaflet: Information for the patient

Sunlenca 300 mg film-coated tablets

lenacapavir

▼ 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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Sunlenca is and what it is used for
2. What you need to know before you take Sunlenca
3. How to take Sunlenca
4. Possible side effects
5. How to store Sunlenca
6. Contents of the pack and other information

1. What Sunlenca is and what it is used for

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

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.

2. What you need to know before you take Sunlenca

Do not take Sunlenca

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

Warnings and precautions

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, *Possible side effects*.

Children and adolescents

Do not give this medicine to children under 18 years of age. The use of Sunlenca in patients aged under 18 has not yet been studied, so it is not known how safe and effective the medicine is in this age group.

Other medicines and Sunlenca

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. 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 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.

As a precautionary measure 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 infection can be passed on to the baby through breast milk. 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.

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 Sunlenca

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.

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, *Possible side effects*).

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.

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.

Do not stop taking Sunlenca

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets 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

(may affect up to 1 in 10 people)

- **Feeling sick** (nausea)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the *Yellow Card Scheme*, Website: www.mhra.gov.uk/yellowcard or search for *MHRA Yellow Card* in the Google Play or Apple App Store.

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

5. How to store Sunlenca

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

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 temperature storage conditions. 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. Contents of the pack and other information

What Sunlenca contains

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

The other ingredients are

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 Sunlenca 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.

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