Patient Information Leaflet

SCHEDULING STATUS

S4

Lenacapavir 300 mg Tablet Gilead

Lenacapavir

Contains sugar (mannitol: 638 mg per tablet)

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, pharmacist, nurse or other healthcare provider.
- Lenacapavir Gilead has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What Lenacapavir Gilead is and what it is used for

Lenacapavir Gilead contains the active substance lenacapavir. It is a long acting antiretroviral medicine known as a capsid inhibitor.

Lenacapavir Gilead is in combination with safer practices to **prevent HIV-1 infection in adults and adolescents** weighing at least 35 kg. This is called *pre-exposure prophylaxis (PrEP)*.

Your doctor will advise you to take Lenacapavir Gilead tablets when you are given Lenacapavir Gilead injections for the first time.

If you are being given Lenacapavir Gilead injections, but you plan to miss your scheduled Lenacapavir Gilead injections, you can take Lenacapavir Gilead tablets instead, until you can receive the injections again (see section 3).

2. What you need to know before you take Lenacapavir Gilead

Do not take Lenacapavir Gilead:

- If you are **allergic** to lenacapavir or any of the other ingredients of Lenacapavir Gilead (listed in section 6).
- If you **do not know if you have HIV**. **You must get tested** to make sure that you do not already have HIV. Lenacapavir Gilead can only prevent HIV if you don't already have it.
- If you are taking any of these medicines:
    - **carbamazepine**, **phenytoin**, used to prevent seizures
    - **St. John's wort** (*Hypericum perforatum*), a herbal remedy used for depression and anxiety

→ **Do not take Lenacapavir Gilead and tell your doctor or nurse immediately** if you think any of these apply to you**.**

Warnings and precautions

- **Take extra measures to prevent HIV while you are receiving Lenacapavir Gilead**
- **Get tested for HIV** when your doctor or nurse tells you. You must get tested regularly to make sure that you stay HIV negative while receiving Lenacapavir Gilead.
- **Get tested for other sexually transmitted infections** when your doctor or nurse tells you to.
- **Keep all your appointments** to get your Lenacapavir Gilead injections on time. Talk to your doctor or nurse if you are thinking about stopping injections: stopping may increase your risk of getting HIV. If you do stop, or miss your scheduled Lenacapavir Gilead injections appointment, you may need to take other medicines or precautions to reduce your risk of getting HIV, and possibly developing viral resistance.
- **Tell your doctor or nurse straight away** if you think you might have HIV (you may get a flu-like illness). They may want to do more tests to make sure you still do not have HIV.

Talk to your doctor or nurse if you have any more questions about how to prevent getting HIV.

- **Lenacapavir Gilead is a long-acting medicine**

  If you stop Lenacapavir Gilead injections, lenacapavir (the active substance in Lenacapavir Gilead) may remain in your body for a year

or more after your last injection, but the amount of drug in your body may be too low to protect you from getting HIV.

Children and adolescents

Do not give this medicine to anyone weighing less than 35 kg because it has not been studied in these individuals.

Other medicines and Lenacapavir Gilead

Always tell your healthcare provider if you are taking, have recently taken or might take any other medicines (this includes complementary and traditional medicines). Lenacapavir Gilead may interact with other medicines. This may keep Lenacapavir Gilead or other medicines from working properly, or may make side effects worse. In some cases, your doctor or nurse may need to adjust your dose or check your blood levels.

Medicines that must never be taken with Lenacapavir Gilead:

- **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 Lenacapavir Gilead and tell your doctor or nurse immediately**.

Talk to your doctor or nurse in particular if you are taking:

- medicines used to treat some bacterial infections, such as tuberculosis, containing:

- rifabutin, rifampicin or rifapentine

- anticonvulsants used to treat epilepsy and prevent seizures (fits), containing:
  - oxcarbazepine or phenobarbital
- medicines used to treat migraine headache, containing:
  - dihydroergotamine or ergotamine
- medicines 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
- antidysrhythmics 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 or nurse if you are taking any of these medicines** or if you start taking any of these medicines while receiving Lenacapavir Gilead. Do not stop any treatment without contacting your doctor or nurse.

Lenacapavir Gilead is a long-acting medicine. If after talking to your doctor or nurse you decide to stop taking Lenacapavir Gilead, you should know low levels of lenacapavir can remain in your system for many months after your last injection. Some other medicines may be affected by the low levels of lenacapavir in your system if you take them within 9 months after your last Lenacapavir Gilead injection. You should check with your doctor or nurse if such medicines are safe for you to take after you stop Lenacapavir Gilead.

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, nurse, pharmacist or other healthcare provider for advice before taking this medicine.

If you are breast-feeding, or thinking about breast-feeding, you should discuss it with your doctor or nurse.

Driving and using machines

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

Lenacapavir Gilead 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 Lenacapavir Gilead

You must have a negative HIV test before taking Lenacapavir Gilead.

You will take tablets by mouth and your doctor or nurse will give you injections under the skin (subcutaneously) when you start Lenacapavir Gilead. After that, you will have injections every 6 months.

Day 1:

- **Two tablets** taken by mouth. These can be taken with or without food.
- **Two injections** given by your doctor or nurse. The two injections will be given at the same time at least 5 centimetres apart from each other and may be given into your abdomen (tummy) or upper buttocks.

Day 2:

- **Two tablets** taken by mouth, as above.

Every 6 months:

- **Two injections** given by your doctor or nurse, as above.

It is important to keep your scheduled appointments every 6 months (26 weeks) to receive your injections of Lenacapavir Gilead. This will continue to help to prevent you from getting HIV.

- Schedule your appointment with your doctor or nurse to make sure you will receive your next injections on time.
- You must receive your next injections within 28 weeks of your last injection.

If you take more Lenacapavir Gilead than you should

Contact your doctor, nurse or pharmacist immediately for advice. If you take more than the recommended dose of Lenacapavir Gilead, you may be at higher risk of side effects (see section 4, Possible side effects).

It is important not to miss a dose of Lenacapavir Gilead tablets.

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

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

If you miss a Lenacapavir Gilead injection appointment

- If you think you will not be able to attend your appointment for your injections, contact your doctor or nurse as soon as possible to discuss your options. If you need to miss a scheduled injection appointment, there is the option to temporarily take Lenacapavir Gilead tablets instead.
- **Using Lenacapavir Gilead tablets if you have to miss an injection appointment**

  - Take one tablet by mouth, every 7 days until your injections resume. Tablets can be taken with or without food.

- It is important to continue Lenacapavir Gilead as your doctor or nurse recommends.

Do not stop taking Lenacapavir Gilead without talking to your doctor or nurse.

Take Lenacapavir Gilead for as long as your doctor or nurse recommends. Do not stop unless your doctor or nurse advises you to. Missing Lenacapavir Gilead injections or tablets increases your risk of getting HIV.

4. Possible side effects

Lenacapavir Gilead can have side effects.

Should your general health worsen or if you experience any untoward effects while taking Lenacapavir Gilead, please consult your healthcare provider for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

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

5. How to store Lenacapavir Gilead

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 bottle label after EXP.

The expiry date refers to the last day of that month.

Store below 30 °C. 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 Lenacapavir Gilead contains

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

The other ingredients are

Tablet core
Mannitol (E421), microcrystalline cellulose (E460), croscarmellose sodium (E468), copovidone, magnesium stearate (E572), poloxamer (see section 2, *Lenacapavir Gilead 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 Lenacapavir Gilead looks like and contents of the pack

Lenacapavir Gilead 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. Lenacapavir Gilead comes in a bottle of 4 tablets. Each bottle contains a silica gel desiccant that must be kept in the bottle to help protect your tablets. The silica gel desiccant is contained in a separate packet and should not be swallowed.

Holder of Certificate of Registration

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This leaflet was last revised in

Not applicable

Registration Number

60/20.2.8/0811

Access to the corresponding Professional Information

The corresponding professional information is included with the pack.

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