Patient Information Leaflet

SCHEDULING STATUS

S4

Lenacapavir 464 mg solution for injection Gilead

Lenacapavir

Sugar free

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

2. What you need to know before you are given Lenacapavir Gilead

Do not receive 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 receive 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 injection 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 receive Lenacapavir Gilead injection 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 injection, that is to say essentially 'sodium-free'.

3. How Lenacapavir Gilead is given

You must have a negative HIV test before being given 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 are given more Lenacapavir Gilead injection than you should

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, speak to your doctor or a nurse.

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.

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

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

Keep receiving Lenacapavir Gilead injections 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.

Not all side effects reported for Lenacapavir Gilead are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Lenacapavir Gilead, please consult your healthcare provider for advice.

Very common side effects

(may affect more than 1 in 10 people)

Tell your doctor if you notice any of the following:

• Reactions where Lenacapavir Gilead is injected

Symptoms may include:

- a hardened mass or lump
- pain and discomfort

- inflammatory reaction such as redness, itching, and swelling

- open sore on the skin

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 vial label and carton 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 light.

6. Contents of the pack and other information

What Lenacapavir Gilead contains

The active substance is lenacapavir.

Each single-use vial contains lenacapavir sodium equivalent to 463.5 mg of lenacapavir.

The other ingredients are

Macrogol (E1521), water for injections.

What Lenacapavir Gilead looks like and contents of the pack

Lenacapavir Gilead solution for injection (injection) is a clear, yellow to brown solution with no visible particles. Lenacapavir Gilead comes in two glass vials, each containing 1.5 ml of solution for injection. These vials are included in an injection kit also containing 2 withdrawal needles (to allow your doctor or a nurse to withdraw Lenacapavir Gilead from the vial), 2 disposable syringes and 2 injection needles.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

The corresponding professional information is included with the pack.

Full instructions for use and handling of Lenacapavir Gilead injection are provided in the professional information (see Instructions for Use).

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