

## Package leaflet: Information for the patient

### Vocabria 600 mg prolonged-release suspension for injection cabotegravir

▼ 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 nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

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

#### 1. What Vocabria is and what it is used for

Vocabria injection contains the active ingredient cabotegravir. Cabotegravir belongs to a group of anti-retroviral medicines called *integrase inhibitors (INIs)*.

Vocabria injection is used to treat HIV (human immunodeficiency virus) infection in adults aged 18 years and over, who are also receiving another antiretroviral medicine called rilpivirine and whose HIV-1 infection is under control.

Vocabria injections do not cure HIV infection; they keep the amount of virus in your body at a low level. This helps maintain the number of CD4 cells in your blood. CD4 cells are a type of white blood cells that are important in helping your body to fight infection.

**Vocabria injection is always given** in combination with another injection of an anti-retroviral medicine called *rilpivirine injection*. Refer to the rilpivirine package leaflet for information on that medicine.

#### 2. What you need to know before you are given Vocabria

##### Do not receive a Vocabria injection:

- if you are **allergic** (*hypersensitive*) to cabotegravir or any of the other ingredients of this medicine (listed in section 6).
- if you are taking any of these medicines as they may affect the way Vocabria works:
  - **carbamazepine, oxcarbazepine, phenytoin, phenobarbital** (medicines to treat epilepsy and prevent fits).
  - **rifampicin or rifapentine** (medicines to treat some bacterial infections such as tuberculosis).

➔ If you think this applies to you, **tell your doctor**.

## Warnings and precautions

### Allergic reaction

Vocabria contains cabotegravir, which is an integrase inhibitor. Integrase inhibitors including cabotegravir can cause a serious allergic reaction known as a *hypersensitivity reaction*. You need to know about important signs and symptoms to look out for while you're receiving Vocabria.

➔ **Read the information** in section 4 of this leaflet.

### Liver problems including hepatitis B and/or C

Tell your doctor if you have or have had problems with your liver, including hepatitis B and/or C. Your doctor may evaluate how severe your liver disease is before deciding if you can take Vocabria.

### Look out for important symptoms

Some people taking medicines for HIV infection develop other conditions, which can be serious. You need to know about important signs and symptoms to look out for while you're taking Vocabria. These include:

- symptoms of infections
- symptoms of liver damage.

➔ **Read the information** in section 4 of this leaflet ('Possible side effects').

If you get any symptoms of infection or liver damage:

➔ **Tell your doctor immediately.** Don't take other medicines for the infection without your doctor's advice.

### Regular appointments are important

It is important that you **attend your planned appointments** to receive your Vocabria 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 Vocabria injection, or if you stop receiving Vocabria, you will need to take other medicines to treat HIV infection and to reduce the risk of developing viral resistance.

**Vocabria injection is a long acting medication.** If you stop treatment, low levels of cabotegravir (the active ingredient of Vocabria) can remain in your system for up to 12 months or more after your last injection. These low levels of cabotegravir will not protect you against the virus and the virus may become resistant. You must start a different HIV treatment within one month of your last Vocabria injection if you are having monthly injections, and within two months of your last Vocabria injection if you are having injections every two months.

### Children and adolescents

This medicine is not for use in children or adolescents less than 18 years of age, because it has not been studied in these patients.

### Other medicines and Vocabria injection

Tell your doctor if you are taking, have recently taken or might take any other medicines including other medicines bought without a prescription.

**Vocabria must not be given** with some other medicines. (see 'Do not receive a Vocabria injection' earlier in section 2).

**Some medicines can affect how Vocabria works** or make it more likely that you will have **side effects**. Vocabria can also affect how some other medicines work.

**Tell your doctor** if you are taking:

- **rifabutin** (to treat some bacterial infections such as tuberculosis).

➔ **Tell your doctor or pharmacist** if you are taking this medicine. Your doctor may decide that you need extra check-ups.

### **Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, think you may be pregnant, or are planning to have a baby:

➔ **Talk to your doctor** before receiving a Vocabria injection

### **Pregnancy**

- **Vocabria is not recommended during pregnancy.** If needed, your doctor will consider the benefit to you and the risk to your baby of receiving Vocabria injections while you're pregnant. If you are planning to have a baby, **talk to your doctor in advance**
- If you have become pregnant, do not stop attending your appointments to receive a Vocabria injection without consulting your doctor.

### **Breast-feeding**

Breast-feeding is **not recommended** in women living with **HIV** because HIV infection can be passed on to the baby in breast milk.

**It is not known** whether the ingredients of Vocabria injection can pass into breast milk. However, it is possible that cabotegravir may still pass into breast milk for 12 months after the last injection of Vocabria.

If you're breast-feeding, or thinking about breast-feeding, you should **discuss it with your doctor as soon as possible**.

### **Driving and using machines**

**Vocabria can make you dizzy** and have other side effects that make you less alert.

➔ **Don't drive or use machines** unless you are sure you're not affected.

## **3. How Vocabria injections are given**

You will be given Vocabria **as an injection**, either once every month or once every 2 months, together with another injection of medicine called rilpivirine. Your doctor will advise you of your dosing schedule.

A nurse or doctor will give you Vocabria through an injection in the muscle of your buttock (*intramuscular, or IM, injection*).

**When you first start treatment** with Vocabria you and your doctor may decide to either start treatment with Vocabria tablets or start treatment directly with a Vocabria injection:

- If you decide to start treatment with tablets, your doctor will tell you:
- to take one 30 mg Vocabria tablet and one 25 mg rilpivirine tablet, once a day, for approximately **one month**
- after that receive **monthly or every 2 month injections**.

This first month of Vocabria and rilpivirine tablets is called the oral **lead-in period**. It allows your doctor to assess whether it's appropriate to proceed with injections.

### Injection schedule for monthly dosing

When		
Which medicine	First injection	Second injection onwards, every month
Vocabria	600 mg injection	400 mg injection every month
Rilpivirine	900 mg injection	600 mg injection every month

### Injection Schedule for every 2 month dosing

Which medicine	When	
	First and second injections, one month apart	Third injection onwards, every two months
Vocabria	600 mg injection	600 mg injection every 2 months
Rilpivirine	900 mg injection	900 mg injection every 2 months

### If you miss a Vocabria injection

➔ **Contact your doctor immediately** to make a new appointment

It is important that you keep your regular planned appointments to receive your injection to control your HIV and to stop your illness from getting worse. Talk to your doctor if you are thinking about stopping treatment.

**Talk to your doctor** if you think you will not be able to receive your Vocabria injection at the usual time. Your doctor may recommend you take Vocabria tablets or another HIV treatment instead, until you are able to receive Vocabria injection again.

### If you are given too much Vocabria injection

A doctor or nurse will give this medicine to you, so it is unlikely that you will be given too much. If you are worried, tell the doctor or nurse.

### Don't stop receiving Vocabria injections without advice from your doctor.

Keep receiving Vocabria injections for as long as your doctor recommends. Don't stop unless your doctor advises you to. If you stop, your doctor must start you on another HIV treatment within a month of your last Vocabria injection if you are having monthly injections, and within two months of your last Vocabria injection if you are having injections every two months, to reduce the risk of developing viral resistance.

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

## 4. Possible side effects

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

### Allergic reactions

Vocabria contains cabotegravir, which is an integrase inhibitor. Integrase inhibitors including cabotegravir can cause a serious allergic reaction known as a hypersensitivity reaction.

If you get any of the following symptoms:

- skin reaction (*rash, hives*)
- a high temperature (*fever*)
- lack of energy (*fatigue*)
- swelling, sometimes of the face or mouth (*angioedema*), causing difficulty in breathing
- muscle or joint aches.

➔ **See a doctor straight away.** Your doctor may decide to carry out tests to check your liver, kidneys or blood, and may tell you to stop taking Vocabria.

### **Very common side effects**

These may affect **more than 1 in 10** people:

- headache
- injection site reactions. In clinical studies, these were generally mild to moderate and became less frequent over time. Symptoms may include:
  - very common: pain and discomfort, a hardened mass or lump
  - common: redness, itching, swelling, warmth, bruising, (which may include discolouration or a collection of blood under the skin)
  - uncommon: numbness, minor bleeding, an abscess (collection of pus) or cellulitis (heat, swelling or redness).
- feeling hot (*pyrexia*), which may occur within one week after injections.

### **Common side effects**

These may affect **up to 1 in 10** people:

- depression
- anxiety
- abnormal dreams
- difficulty in sleeping (*insomnia*)
- dizziness
- feeling sick (*nausea*)
- vomiting
- stomach pain (*abdominal pain*)
- wind (*flatulence*)
- diarrhoea
- rash
- muscle pain (*myalgia*)
- lack of energy (*fatigue*)
- feeling weak (*asthenia*)
- generally feeling unwell (*malaise*)
- weight gain.

### **Uncommon side effects**

These may affect **up to 1 in 100** people:

- suicide attempt and suicidal thoughts (particularly in patients who have had depression or mental health problems before)
- allergic reaction (*hypersensitivity*)
- hives (*urticaria*)
- swelling, sometimes of the face or mouth (*angioedema*), causing difficulty in breathing
- feeling drowsy (*somnolence*)
- feeling lightheaded, during or following an injection. This may lead to fainting
- liver damage (signs may include yellowing of the skin and the whites of the eyes, loss of appetite, itching, tenderness of the stomach, light-coloured stools or unusually dark urine)

- changes in liver blood tests (increase in *transaminases* or increase in *bilirubin*).

#### **Other side effects that may show up in blood tests**

- an increase in lipases (a substance produced by the pancreas)

#### **Other possible side effects**

People receiving Vocabria and rilpivirine therapy for HIV may get other side effects.

#### **Pancreatitis**

If you get severe pain in the abdomen (tummy), this may be caused by inflammation of your pancreas (pancreatitis).

➔ **Tell your doctor**, especially if the pain spreads and gets worse.

#### **Symptoms of infection and inflammation**

People with advanced HIV infection (AIDS) have weak immune systems and are more likely to develop serious infections (*opportunistic infections*). When they start treatment, the immune system becomes stronger, so the body starts to fight infections.

Symptoms of infection and inflammation may develop, caused by either:

- old, hidden infections flaring up again as the body fights them
- the immune system attacking healthy body tissue (*autoimmune disorders*).

The symptoms of autoimmune disorders may develop many months after you start taking medicine to treat your HIV infection.

Symptoms may include:

- **muscle weakness** and/or **muscle pain**
- **joint pain** or **swelling**
- **weakness** beginning in the hands and feet and moving up towards the trunk of the body
- **palpitations** or **tremor**
- **hyperactivity** (excessive restlessness and movement).

#### **If you get any symptoms of infection:**

➔ **Tell your doctor immediately.** Don't take other medicines for the infection without your doctor's advice.

#### **Reporting of side effects**

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://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 Vocabria**

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 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.

Do not freeze.

## **6. Contents of the pack and other information**

### **What Vocabria contains**

- The active substance is cabotegravir.

Each 3 ml vial contains 600 mg cabotegravir.

The other ingredients are:

Mannitol (E421)

Polysorbate 20 (E432)

Macrogol (E1521)

Water for injections

### **What Vocabria looks like and contents of the pack**

Cabotegravir prolonged release suspension for injection is presented in a brown glass vial with a rubber stopper. The pack also contains 1 syringe, 1 vial adaptor, and 1 injection needle.

### **Marketing Authorisation Holder**

ViiV Healthcare UK Limited

980 Great West Road

Brentford

Middlesex

TW8 9GS

United Kingdom

### **Manufacturer**

Glaxo Operations UK Limited (trading as Glaxo Wellcome Operations)

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Barnard Castle

County Durham DL12 8DT

UK

GlaxoSmithKline Manufacturing SpA

Strada Provinciale Asolana, 90

San Polo di Torrile

Parma, 43056

Italy

### **Other formats**

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:

**Product name**            **Vocabria 600mg Injection**

**Reference number**      35728/0057

This is a service provided by the Royal National Institute of Blind People.

**This leaflet was last revised in June 2023.**

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The following information is intended for healthcare professionals only:

### Vocabria 3 mL injection Instructions for use:

#### Overview

A complete dose requires two injections: **VOCABRIA and rilpivirine**

3 mL of cabotegravir and 3 mL of rilpivirine.

Cabotegravir and rilpivirine are suspensions that do not need further dilution or reconstitution. The preparation steps for both medicines are the same.

Cabotegravir and rilpivirine are for intramuscular use only. Both injections must be administered to the gluteal sites. The administration order is not important.

**Note:** The ventrogluteal site is recommended.

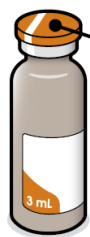


#### Storage information

- This medicine does not require any special storage conditions.

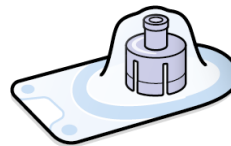
**Do not freeze.**

#### Cabotegravir vial

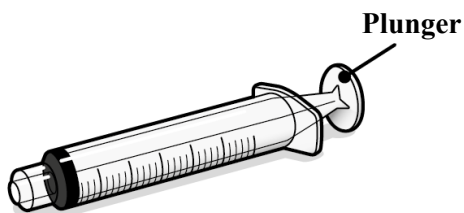


**Vial cap**  
(Rubber stopper under cap)

#### Vial adaptor

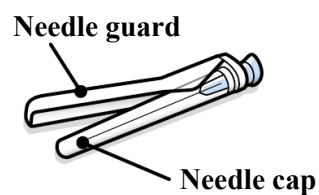


#### Syringe



**Plunger**

#### Injection needle



**Needle guard**

**Needle cap**

### Your pack contains

- 1 vial of cabotegravir
- 1 vial adaptor
- 1 syringe
- 1 injection needle (0.65 mm, 38 mm [23 gauge, 1.5 inches])

Consider the patient's build and use medical judgment to select an appropriate injection needle length.

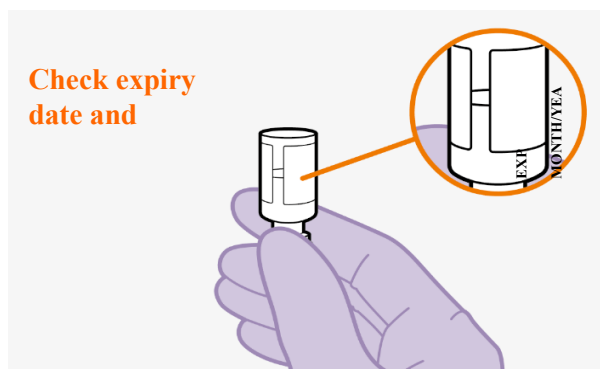
### You will also need

- Non-sterile gloves
  - 2 alcohol swabs
  - 2 gauze pads
  - A suitable sharps container
  - 1 rilpivirine 3 mL pack
- Make sure to have the rilpivirine pack close by before starting.

### Preparation

#### 1. Inspect vial

Check expiry date and



- Check that the expiry date has not passed.
- Inspect the vial immediately. If you can see foreign matter, do not use the product.

**Note:** The cabotegravir vial has a brown tint to the glass.

**Do not** use if the expiry date has passed.

#### 2. Wait 15 minutes

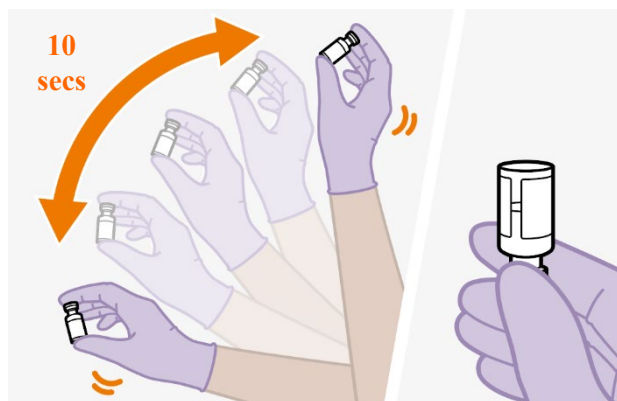


Wait 15 minutes



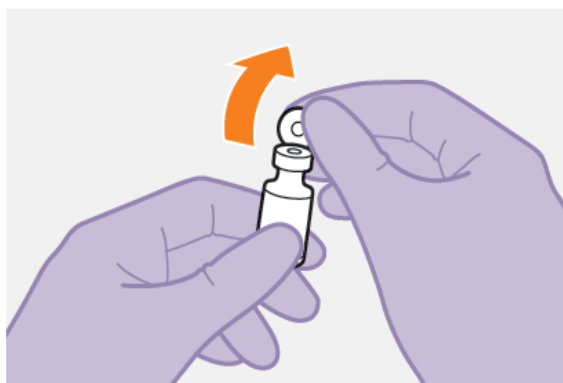
- If the pack has been stored in a fridge, remove and wait at least 15 minutes before you are ready to give the injection to allow the medicine to come to room temperature.

### 3. Shake vigorously



- Hold the vial firmly and vigorously shake for a full 10 seconds as shown.
- Invert the vial and check the resuspension. It should look uniform. If the suspension is not uniform, shake the vial again.
- It is also normal to see small air bubbles.

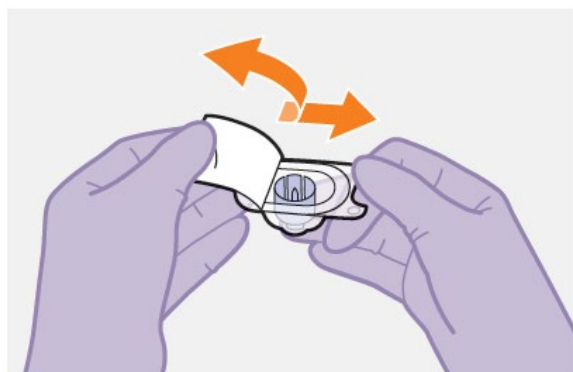
### 4. Remove vial cap



- Remove the cap from the vial.
- Wipe the rubber stopper with an alcohol swab.

**Do not** allow anything to touch the rubber stopper after wiping it.

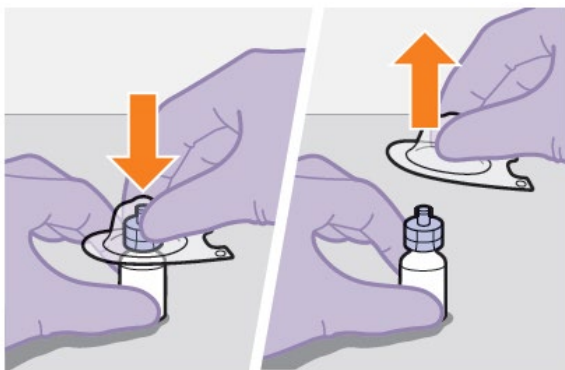
### 5. Peel open vial adaptor



- Peel off the paper backing from the vial adaptor packaging.

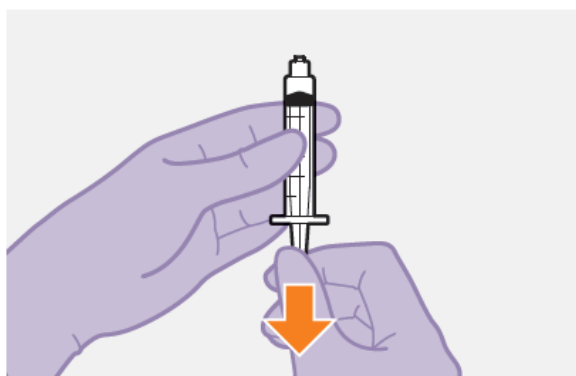
**Note:** Keep the adaptor in place in its packaging for the next step.

## 6. Attach vial adaptor



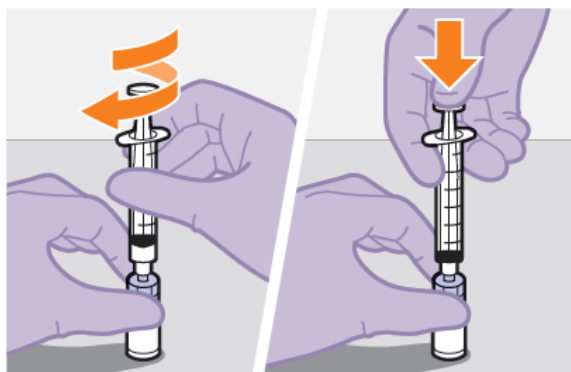
- Press the vial adaptor straight down onto the vial using the packaging, as shown. The vial adaptor should snap securely into place.
- When you are ready, lift off the vial adaptor packaging as shown.

## 7. Prepare syringe



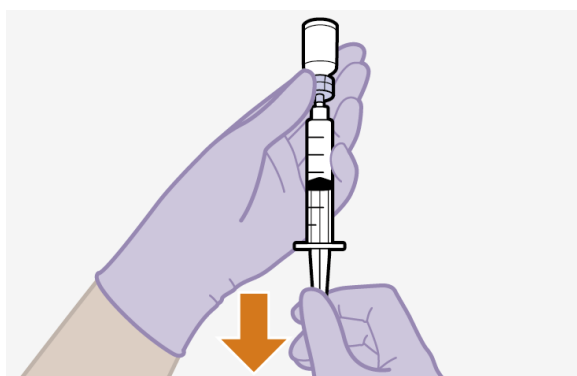
- Remove the syringe from its packaging.
- Draw 1 mL of air into the syringe. This will make it easier to draw up the liquid later.

### 8. Attach syringe



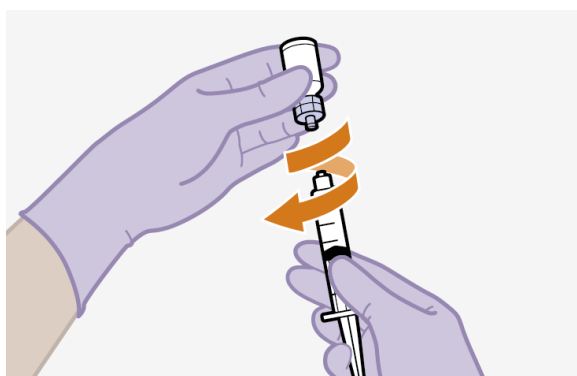
- Hold the vial adaptor and vial firmly, as shown.
- Screw the syringe firmly onto the vial adaptor.
- Press the plunger all the way down to push the air into the vial.

### 9. Slowly draw up dose



- Invert the syringe and vial, and slowly withdraw as much of the liquid as possible into the syringe. There might be more liquid than the dose amount.

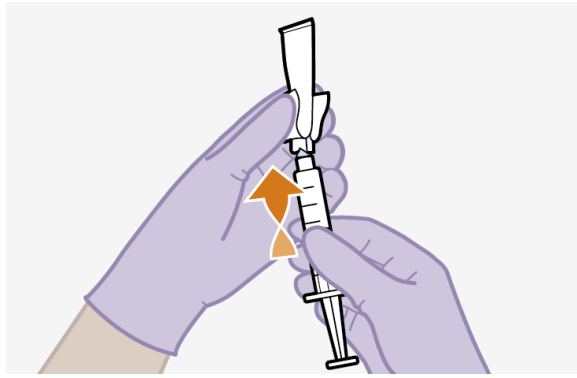
### 10. Unscrew syringe



- Screw the syringe off the vial adaptor, holding the vial adaptor as shown.

**Note:** Keep the syringe upright to avoid leakage. Check that the cabotegravir suspension looks uniform and white to light pink.

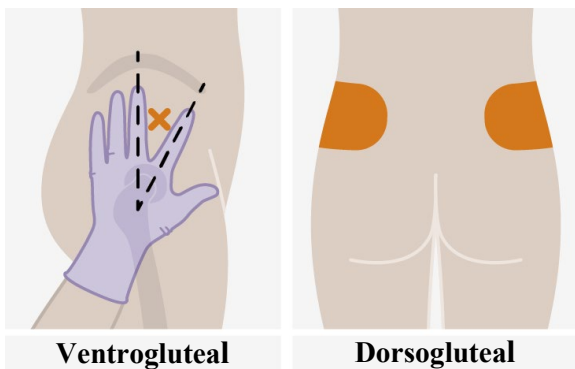
### 11. Attach needle



- Peel open the needle packaging part way to expose the needle base.
- Keeping the syringe upright, firmly twist the syringe onto the needle.
- Remove the needle packaging from the needle.

## Injection

### 12. Prepare injection site



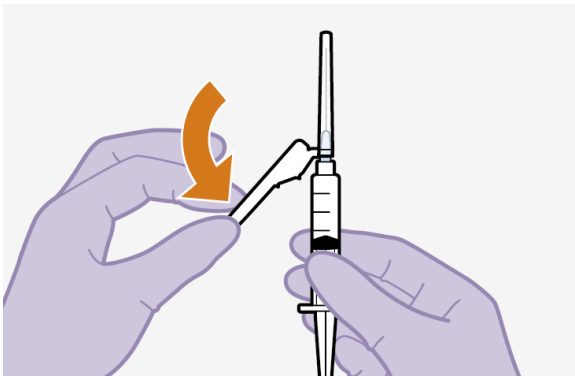
Injections must be administered to the gluteal sites.

Select from the following areas for the injection:

- Ventrogluteal (recommended)
- Dorsogluteal (upper outer quadrant)

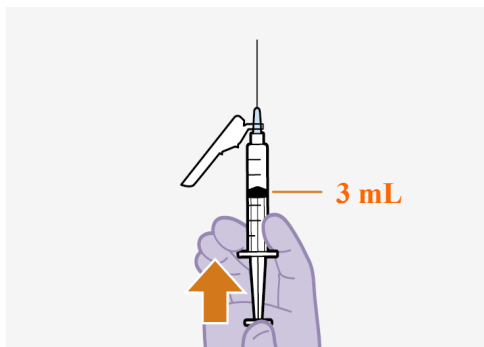
**Note:** For gluteal intramuscular use only.  
**Do not** inject intravenously.

### 13. Remove cap



- Fold the needle guard away from the needle.
- Pull off the injection needle cap.

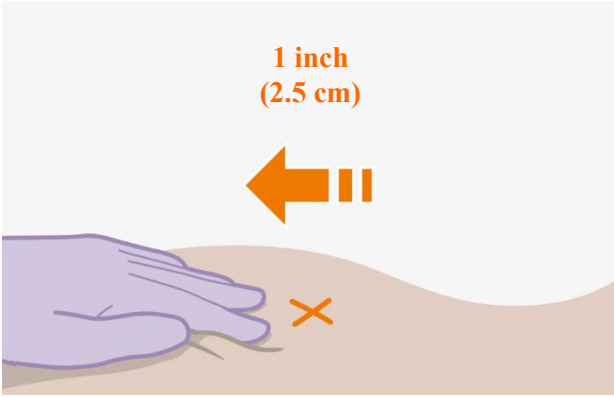
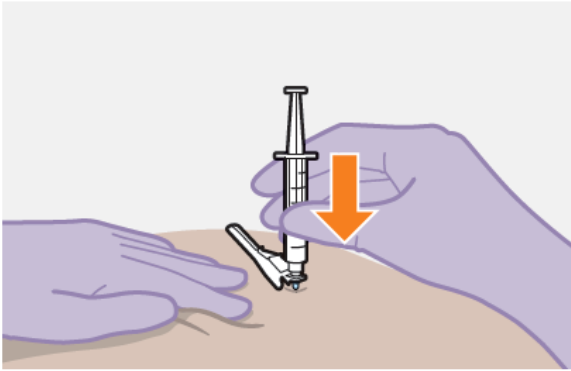
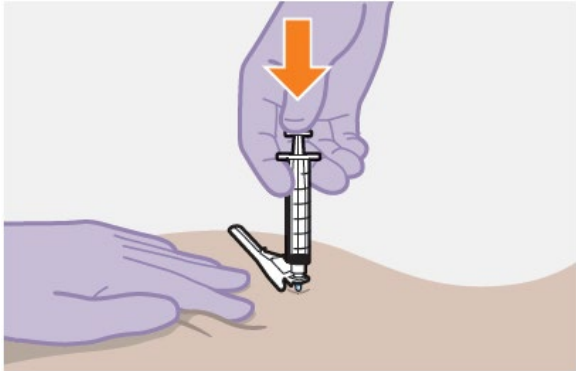
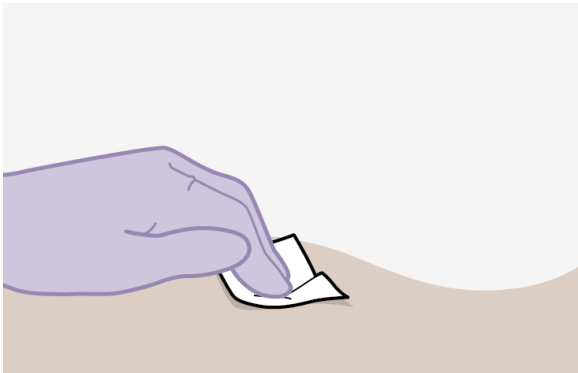
### 14. Remove extra liquid



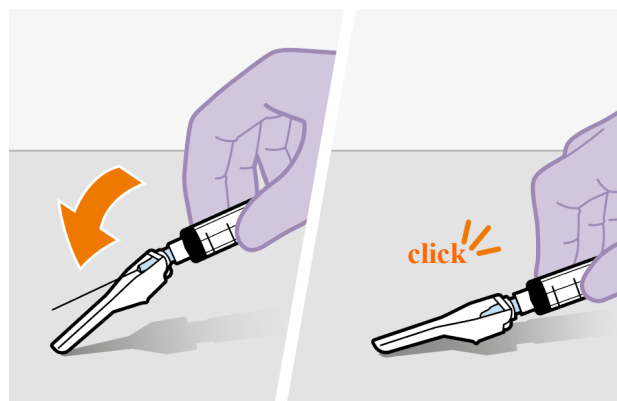
- Hold the syringe with the needle pointing up. Press the plunger to the 3 mL dose to remove extra liquid and any air bubbles.

**Note:** Clean the injection site with an alcohol swab. Allow the skin to air dry before continuing.

### 15. Stretch skin

	<p>Use the z-track injection technique to minimise medicine leakage from the injection site.</p> <ul style="list-style-type: none"> <li>• Firmly drag the skin covering the injection site, displacing it by about an inch (2.5 cm).</li> <li>• Keep it held in this position for the injection.</li> </ul>
<p><b>16. Insert needle</b></p> 	<ul style="list-style-type: none"> <li>• Insert the needle to its full depth, or deep enough to reach the muscle.</li> </ul>
<p><b>17. Inject dose</b></p> 	<ul style="list-style-type: none"> <li>• Still holding the skin stretched – slowly press the plunger all the way down.</li> <li>• Ensure the syringe is empty.</li> <li>• Withdraw the needle and release the stretched skin immediately.</li> </ul>
<p><b>18. Assess the injection site</b></p> 	<ul style="list-style-type: none"> <li>• Apply pressure to the injection site using a gauze.</li> <li>• A small bandage may be used if a bleed occurs.</li> </ul> <p><b>Do not</b> massage the area.</p>

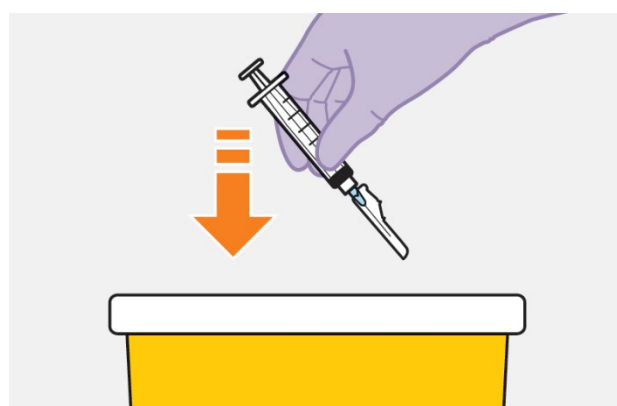
### 19. Make needle safe



- Fold the needle guard over the needle.
- Gently apply pressure using a hard surface to lock the needle guard in place.
- The needle guard will make a click when it locks.

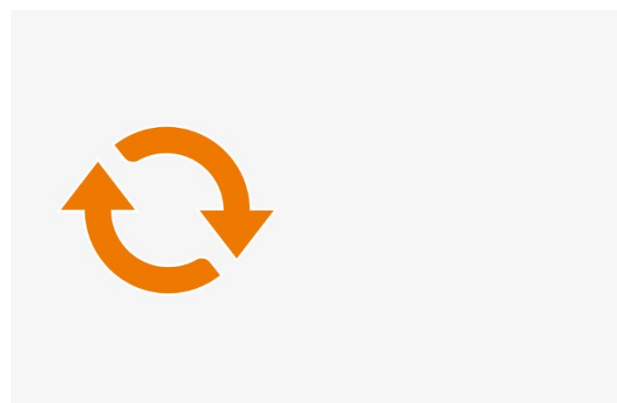
### After injection

### 20. Dispose safely



- Dispose of used needles, syringes, vials and vial adaptors according to local health and safety laws.

### Repeat for 2nd medicine



If you have not yet injected both medicines, use the steps for preparation and injection for Rilpivirine which has its own specific Instructions for Use.

### Questions and Answers

#### 1. How long can the medicine be left in the syringe?

Once the suspension has been drawn into the syringe, the injection should be used immediately, from a microbiological point of view.

Chemical and physical in-use stability has been demonstrated for 2 hours at 25°C.

#### 2. Why do I need to inject air into the vial?

Injecting 1 mL of air into the vial makes it easier to draw up the dose into the syringe.

Without the air, some liquid may flow back into the vial unintentionally, leaving less than intended in the syringe.

#### 3. Does the order in which I give the medicines matter?



No, the order is unimportant.

**4. If the pack has been stored in the fridge, is it safe to warm the vial up to room temperature more quickly?**

It is best to let the vial come to room temperature naturally. However, you can use the warmth of your hands to speed up the warm up time, but make sure the vial does not get above 30°C.

Do not use any other heating methods.

**5. Why is the ventrogluteal administration approach recommended?**

The ventrogluteal approach, into the gluteus medius muscle, is recommended because it is located away from major nerves and blood vessels. A dorso-gluteal approach, into the gluteus maximus muscle, is acceptable, if preferred by the health care professional. The injection should not be administered in any other site.