

**Single Entity Vial Core Instructions for Use**  
**REKAMBYS**  
(rilpivirine)  
**3 mL**  
**prolonged-release suspension for injection**

**The following information is intended for medical or healthcare professionals only and should be read in conjunction with the full prescribing information.**



Prolonged-release suspension for injection

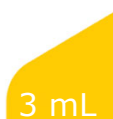
**rilpivirine**

**for gluteal intramuscular use only.**

**Instructions for Use**



You will also need  
**cabotegravir**  
**600 mg (3 mL)**



**Overview**

**A complete dose requires two injections:**

3 mL of cabotegravir and 3 mL of rilpivirine.

Cabotegravir and rilpivirine are suspensions that do not need further dilution or reconstitution.

Cabotegravir and rilpivirine are **for intramuscular use only**.

Both injections should be administered at separate gluteal injection sites.

The administration order is not important.

Use appropriate aseptic technique throughout.

**Storage information**

Store in refrigerator at **2°C to 8°C**.

**Do not** freeze.

**Supplies you need**

**Your package contains**

- 1 vial of rilpivirine

**You will also need (not included in package)**

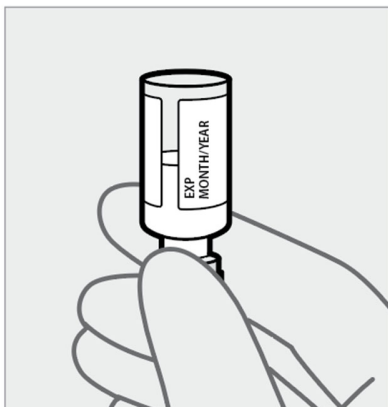
- 1 syringe (5 mL)
- 1 aspiration needle
- 1 injection needle of size 1½ inch (21G-23G)

- Gloves
- 2 alcohol swabs
- 2 gauze pads
- A suitable sharps container
- 1 cabotegravir 3 mL package

**Important notes:**

- Consider the patient's build and use medical judgment to select an appropriate injection needle length.
- Use Luer-Lock syringes and (safety) injection needles, if available.
- Make sure to have the cabotegravir 3 mL package also available before starting.

## 1. Prepare vial

**Inspect vial**

Remove 1 vial package from the refrigerator.

Take the vial out of the carton.

Check the expiry date ('EXP') on the vial.

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

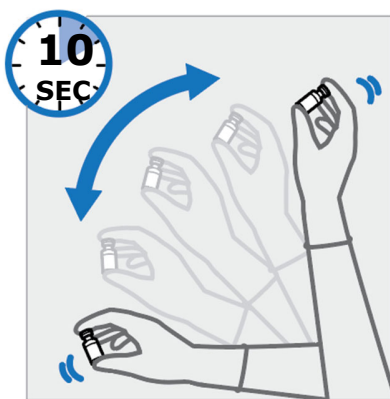


**Leave vial at room temperature for at least 15 minutes to reach room temperature.**

**Place the vial on a flat surface and let it sit at room temperature for at least 15 minutes before use.**

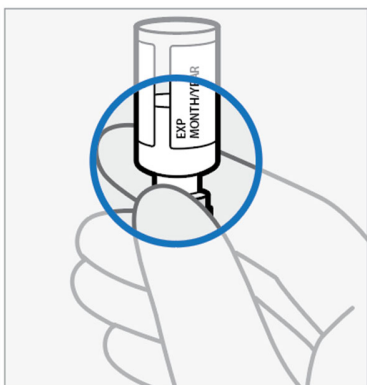
The vial may sit at room temperature (maximum temperature of 25°C) for up to 6 hours.

## 2. Prepare medication for injection



### Shake vigorously

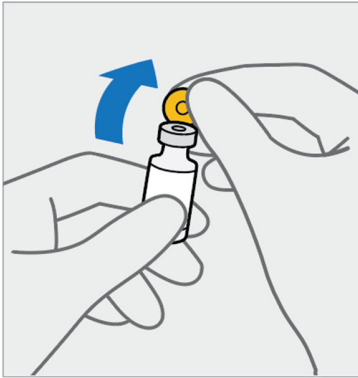
Hold the vial firmly and shake vigorously with a loose wrist and a long arm motion for at least **10 seconds**.



### Check liquid

Check the resuspension with the cap pointing down. It should look uniform and white to off-white in color. You may also see small air bubbles. This is normal.

**If the resuspension is not uniform, shake the vial vigorously again.**



### **Remove vial cap**

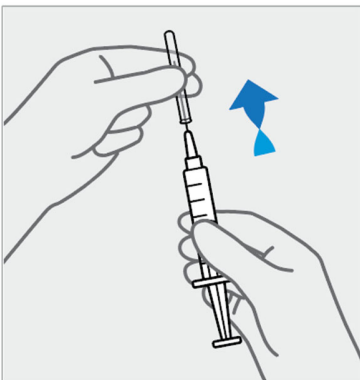
Remove the cap from vial.

Wipe the rubber stopper with an alcohol swab.

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

Before continuing with the next steps, ensure to collect all supplies you need that are not included in the package, as listed in the beginning of the Instructions for Use.

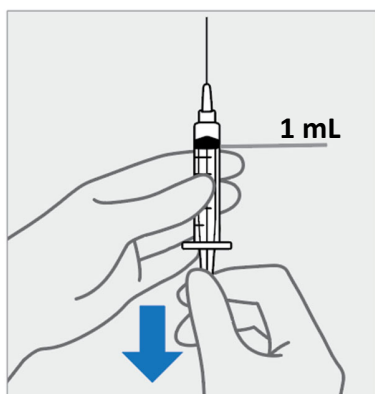
## **3. Prepare syringe**



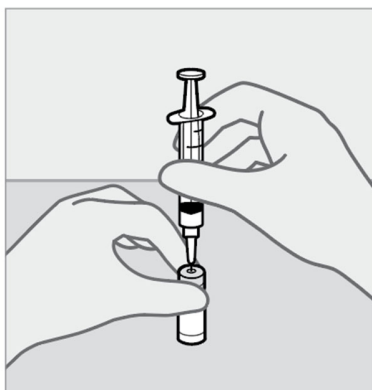
### **Attach aspiration needle**

Hold the syringe upright and firmly attach the syringe onto the needle base.

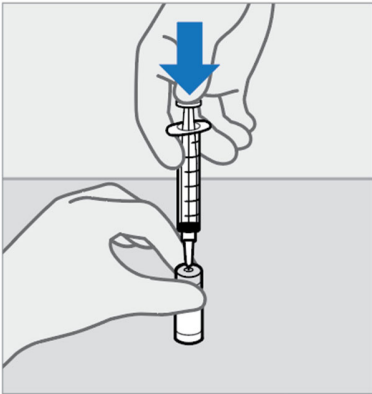
Remove the needle cover.

**Draw air into syringe**

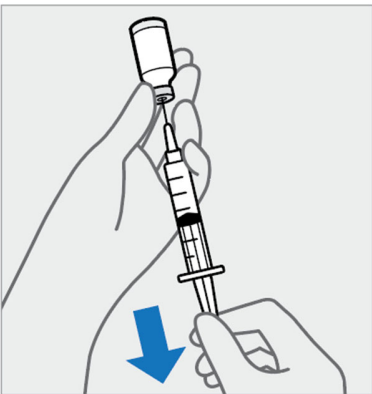
Pull the plunger and draw **1 mL** of air into the syringe.  
Doing so makes it easier to draw up liquid later.

**4. Draw and adjust dose****Insert aspiration needle into vial**

Place the vial on a flat surface.  
Insert the needle into the stopper.

**Push air into vial**

Press plunger all the way down to push the air into the vial.

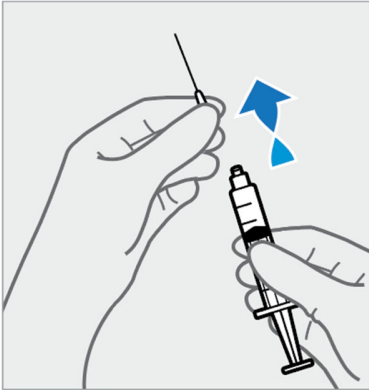
**Draw up liquid**

Invert the syringe and vial.

Firmly hold the barrel of the syringe. Slowly pull the plunger to **withdraw as much liquid as possible** into the syringe.

There may be more liquid in the syringe than the amount needed for one injection dose. This is normal.

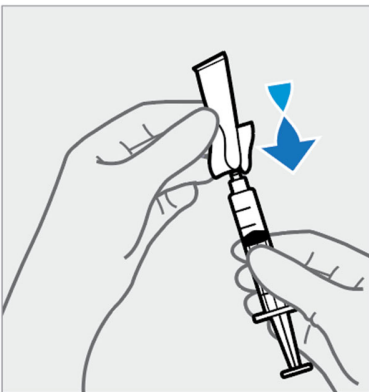
The medication can be in the syringe for up to 2 hours. If more than 2 hours pass, dispose of the filled syringe.

**Remove aspiration needle**

Pull the needle out of the vial stopper.

Detach the needle from the syringe.

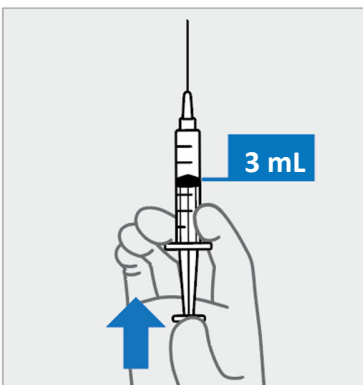
**NOTE:** Keep the syringe upright to avoid leakage.  
Check that the suspension looks uniform and white to off-white.

**Attach injection needle**

Peel the needle packaging half way.

Attach injection needle to syringe.

Remove the needle packaging from the needle.

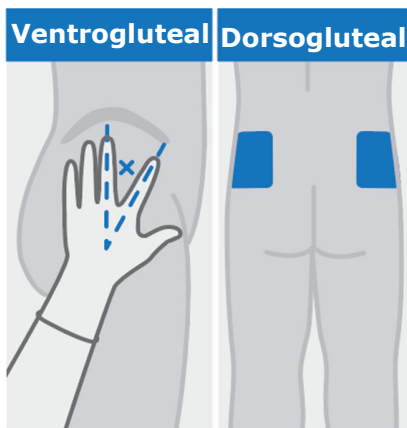


**Adjust dose**

Hold the syringe with the needle pointing up.

Press the plunger to the **3 mL** line to remove extra liquid and any air bubbles.

## 5. Inject rilpivirine in a gluteal site

**Prepare injection site**

Administer the injection to one of the following sites:

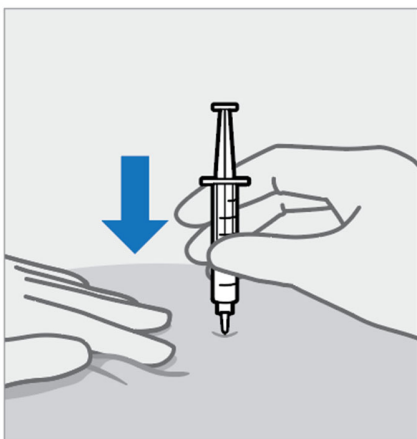
- **Ventrogluteal** (recommended)
- Dorsogluteal (upper outer quadrant)

Clean the injection site with an alcohol swab.  
Allow the skin to air dry.

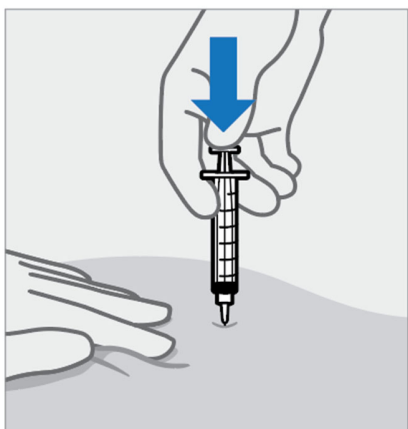
**Stretch skin**

Firmly drag the skin covering the injection site, displacing it by about 2.5 cm (1 inch). This technique minimizes medicine leakage from the injection site. Keep the skin held in this position for the entire injection.



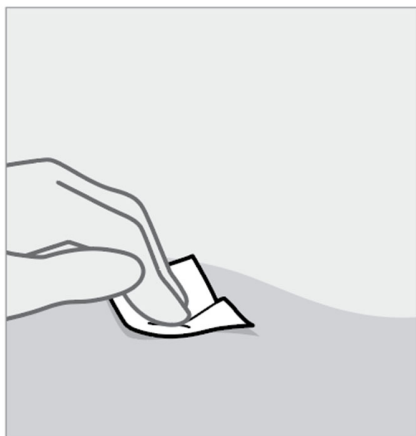
**Insert needle**

Insert the needle to its full depth or deep enough to reach the muscle.

**Inject medication**

Keeping the skin stretched, slowly press the plunger all the way down until it stops.

Remove the needle and immediately let go of the skin.



### **Check injection site**

There may be a small amount of blood or liquid at the injection site.

Hold pressure over the skin with a gauze pad until any bleeding stops.

**Do not** rub the injection site. If needed, cover the injection site with a bandage.

## **6. After the injection**



### **Dispose**

Dispose of the used needles, syringe and vial according to your local health and safety regulations.



### Repeat for cabotegravir injection

If you have not yet injected cabotegravir, refer to the Instructions for Use that come with cabotegravir to complete the treatment.

Inject cabotegravir into a separate ventrogluteal site from the rilpivirine injection site.

### Questions and Answers

#### 1. How long can the medicine be left out of the refrigerator?

It is best to inject the medicine as soon as it reaches room temperature. However, the vial may sit in the carton at room temperature (maximum temperature of 25°C) for up to 6 hours; do not put back into the refrigerator. If not used within 6 hours, the vial must be discarded.

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

It is best to inject the (room temperature) medicine as soon as possible after drawing it up. However, the medicine can remain in the syringe for up to 2 hours before injecting.

If 2 hours are exceeded, the filled syringe and needle must be discarded.

#### 3. 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.

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

No, the order is unimportant.

#### 5. After the package 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 25°C.

Do not use any other heating methods.

**6. 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 healthcare professional. The injection should not be administered in any other site.

Keep out of reach of children.

**List of excipients**

poloxamer 338  
citric acid monohydrate  
glucose monohydrate  
sodium dihydrogen phosphate monohydrate  
sodium hydroxide (to adjust pH and ensure isotonicity)  
water for injections

**Marketing Authorization Number**

1C 15078/67 (NC)

**Date of Authorization**

23-Aug-2024

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**DATE OF REVISION OF THE TEXT**

27 Feb 2024 (SEV IFU V.3, 15-NOV-2023)

**Manufactured by**

Cilag AG, Schaffhausen, Switzerland

**Imported by**

Janssen-Cilag Ltd., Bangkok, Thailand

To report Suspected Adverse Reactions, please contact us at [aepqcjacth@its.jnj.com](mailto:aepqcjacth@its.jnj.com)

For any product information, please contact us at [medinfosea@its.jnj.com](mailto:medinfosea@its.jnj.com)

Please see full prescribing information at <https://ndi.fda.moph.go.th>

**WARNINGS ACCORDING TO MINISTRY OF PUBLIC HEALTH ANNOUNCEMENT**

This product can cause severe liver toxicity.

**Single Entity Vial Core Instructions for Use**  
**REKAMBYS**  
 (rilpivirine)  
**2 mL**  
**prolonged-release suspension for injection**

**The following information is intended for medical or healthcare professionals only and should be read in conjunction with the full prescribing information.**

 **REKAMBYS**

**600 mg**

Prolonged-release suspension for injection

**rilpivirine**

**for gluteal intramuscular use only.**

**Instructions for Use**



You will also need  
**cabotegravir**  
**600 mg (2 mL)**

**2 mL**

**Overview**

**A complete dose requires two injections:**

2 mL of cabotegravir and 2 mL of rilpivirine.

Cabotegravir and rilpivirine are suspensions that do not need further dilution or reconstitution.

Cabotegravir and rilpivirine are **for intramuscular use only**.

Both injections should be administered at separate gluteal injection sites.

The administration order is not important.

Use appropriate aseptic technique throughout.

**Storage information**

Store in refrigerator at **2°C to 8°C**.

**Do not** freeze.

**Supplies you need**

**Your package contains**

- 1 vial of rilpivirine

**You will also need (not included in package)**

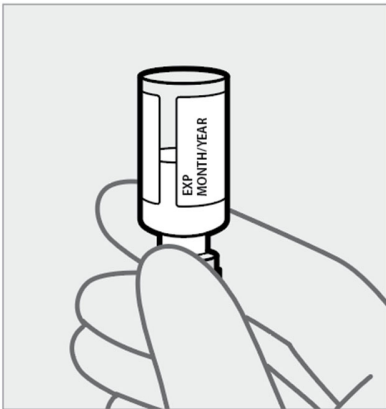
- 1 syringe (5 mL)
- 1 aspiration needle

- 1 injection needle of size 1½ inch (21G-23G)
- Gloves
- 2 alcohol swabs
- 2 gauze pads
- A suitable sharps container
- 1 cabotegravir 2 mL package

**Important notes:**

- Consider the patient's build and use medical judgment to select an appropriate injection needle length.
- Use Luer-Lock syringes and (safety) injection needles, if available.
- Make sure to have the cabotegravir 2 mL package also available before starting.

## 1. Prepare vial

**Inspect vial**

Remove 1 vial package from the refrigerator.

Take the vial out of the carton.

Check the expiry date ('EXP') on the vial.

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

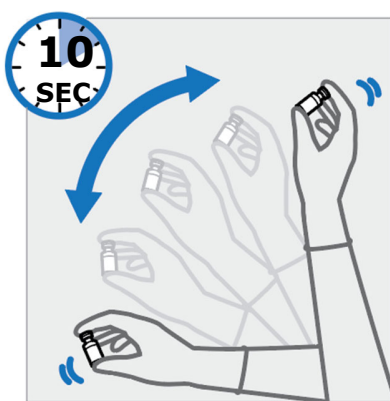


**Leave vial at room temperature  
for at least 15 minutes to reach room temperature**

**Place the vial on a flat surface and let it  
sit at room temperature  
for at least 15 minutes before use.**

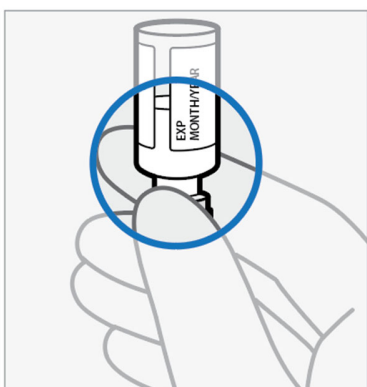
The vial may sit at room temperature  
(maximum temperature of 25°C)  
for up to 6 hours.

## 2. Prepare medication for injection



### Shake vigorously

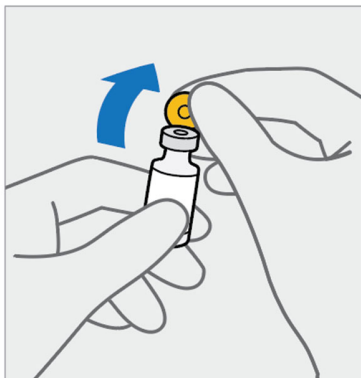
Hold the vial firmly and shake vigorously  
with a loose wrist and a long  
arm motion for at least **10 seconds**.



### Check liquid

Check the resuspension with the cap  
pointing down. It should look uniform  
and white to off-white in color. You may  
also see small air bubbles. This is normal.

**If the resuspension is not uniform, shake the vial vigorously again.**



### **Remove vial cap**

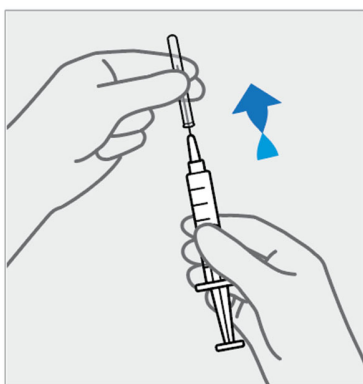
Remove the cap from vial.

Wipe the rubber stopper with an alcohol swab.

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

Before continuing with the next steps, ensure to collect all supplies you need that are not included in the package, as listed in the beginning of the Instructions for Use.

## **3. Prepare syringe**

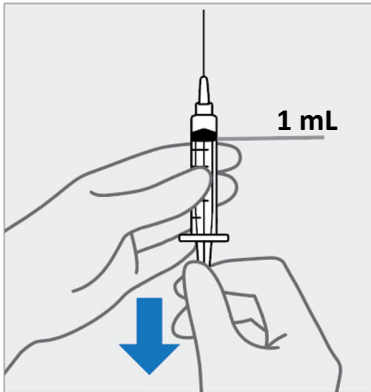


### **Attach aspiration needle**

Hold the syringe upright and firmly attach the syringe onto the needle base.



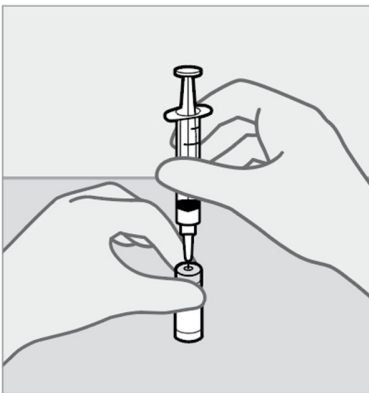
Remove the needle cover.



#### **Draw air into syringe**

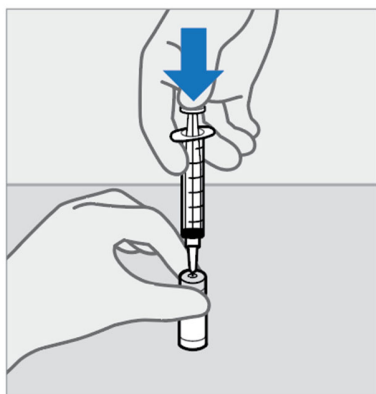
Pull the plunger and draw **1 mL** of air into the syringe. Doing so makes it easier to draw up liquid later.

## **4. Draw and adjust dose**

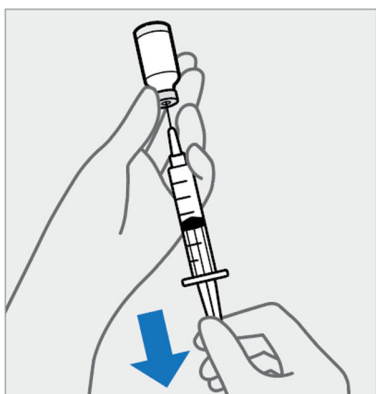


#### **Insert aspiration needle into vial**

Place the vial on a flat surface.  
Insert the needle into the stopper.

**Push air into vial**

Press plunger all the way down to push the air into the vial.

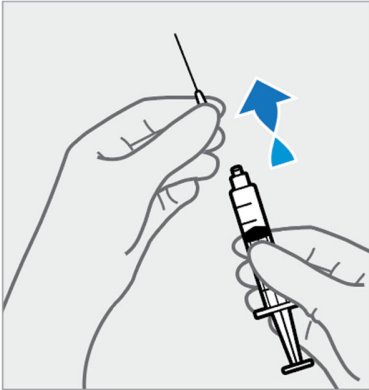
**Draw up liquid**

Invert the syringe and vial.

Firmly hold the barrel of the syringe. Slowly pull the plunger to **withdraw as much liquid as possible** into the syringe.

There may be more liquid in the syringe than the amount needed for one injection dose. This is normal.

The medication can be in the syringe for up to 2 hours. If more than 2 hours pass, dispose of the filled syringe.

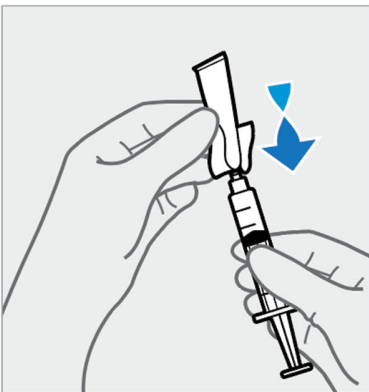
**Remove aspiration needle**

Pull the needle out of the vial stopper.

Detach the needle from the syringe.

**NOTE:** Keep the syringe upright to avoid leakage.

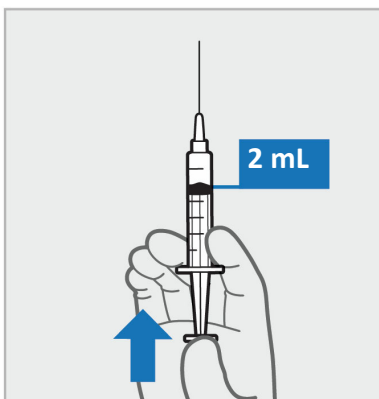
Check that the suspension looks uniform and white to off-white.

**Attach injection needle**

Peel the needle packaging half way.

Attach injection needle to syringe.

Remove the needle packaging from the needle.

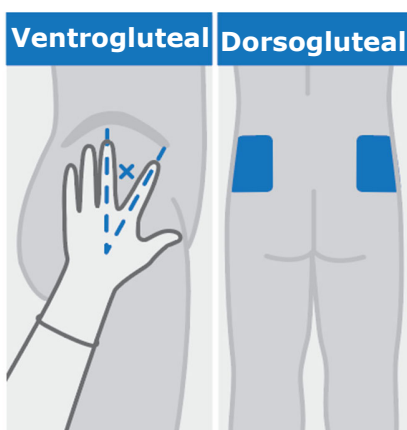


**Adjust dose**

Hold the syringe with the needle pointing up.

Press the plunger to the **2 mL** line to remove extra liquid and any air bubbles.

## 5. Inject rilpivirine in a gluteal site

**Prepare injection site**

Administer the injection to one of the following sites:

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

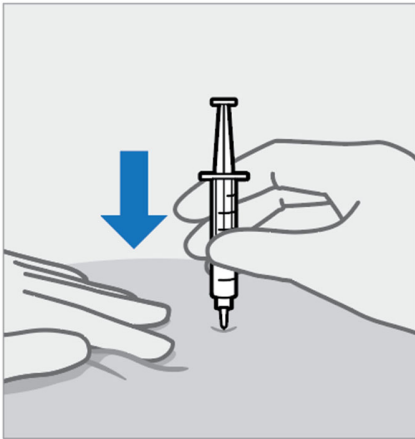
Clean the injection site with an alcohol swab.

Allow the skin to air dry.

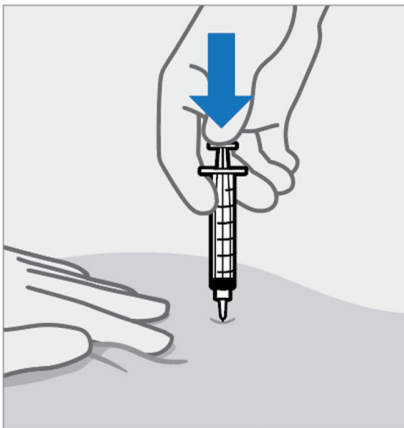
**Stretch skin**

Firmly drag the skin covering the injection site, displacing it by about 2.5 cm (1 inch). This technique minimizes medicine leakage from the injection site.

Keep the skin held in this position for the entire injection.

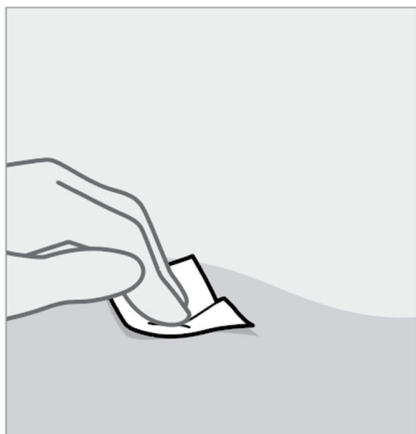
**Insert needle**

Insert the needle to its full depth or deep enough to reach the muscle.

**Inject medication**

Keeping the skin stretched, slowly press the plunger all the way down until it stops.

Remove the needle and immediately let go of the skin.

**Check injection site**

There may be a small amount of blood or liquid at the injection site.

Hold pressure over the skin with a gauze pad until any bleeding stops.

**Do not** rub the injection site. If needed, cover the injection site with a bandage.

## 6. After the injection

**Dispose**

Dispose of the used needles, syringe and vial according to your local health and safety regulations.



### **Repeat for cabotegravir injection**

If you have not yet injected cabotegravir, refer to the Instructions for Use that come with cabotegravir to complete the treatment.

Inject cabotegravir into a separate ventrogluteal site from the rilpivirine injection site.

### **Questions and Answers**

#### **1. How long can the medicine be left out of the refrigerator?**

It is best to inject the medicine as soon as it reaches room temperature. However, the vial may sit in the carton at room temperature (maximum temperature of 25°C) for up to 6 hours; do not put back into the refrigerator. If not used within 6 hours, the vial must be discarded.

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

It is best to inject the (room temperature) medicine as soon as possible after drawing it up. However, the medicine can remain in the syringe for up to 2 hours before injecting.

If 2 hours are exceeded, the filled syringe and needle must be discarded.

#### **3. 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.

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

No, the order is unimportant.

#### **5. After the package 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 25°C.

Do not use any other heating methods.

**6. 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 healthcare professional. The injection should not be administered in any other site.

Keep out of reach of children

**List of excipients**

poloxamer 338  
citric acid monohydrate  
glucose monohydrate  
sodium dihydrogen phosphate monohydrate  
sodium hydroxide (to adjust pH and ensure isotonicity)  
water for injections

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To report Suspected Adverse Reactions, please contact us at [aepqcjacth@its.jnj.com](mailto:aepqcjacth@its.jnj.com)

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Please see full prescribing information at <https://ndi.fda.moph.go.th>

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