

Core Single Entity Vial Instructions for Use
REKAMBYS® prolonged-release suspension
for injection 300mg/mL
(rilpivirine)

2 mL

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

Overview

Two injections are required to complete treatment at a visit: cabotegravir 2 mL and rilpivirine 2 mL. 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 (see pictogram in step 6 *Prepare injection site*).

List of excipients for REKAMBYS®: citric acid monohydrate, glucose monohydrate, poloxamer 338, sodium dihydrogen phosphate monohydrate, sodium hydroxide, water for injections



Storage information

- Store in refrigerator at 2°C to 8°C. Keep out of the sight and reach of children.

 **Do not** freeze.

Your package contains

- 1 vial of rilpivirine

To prepare the injection ensure you have the following devices (not included in package)

- One 5 mL syringe (Luer-Lock if available)
- 1 aspiration needle (Luer-Lock if available) or aspiration device (to draw up the suspension)

To administer the injection ensure you have the following device (not included in package)

- 1 additional needle (use Luer-Lock and/or safety needle if available) of 21-23 gauge, 1.5 inches
- Consider the patient's build and use medical judgment to select an appropriate injection needle length.

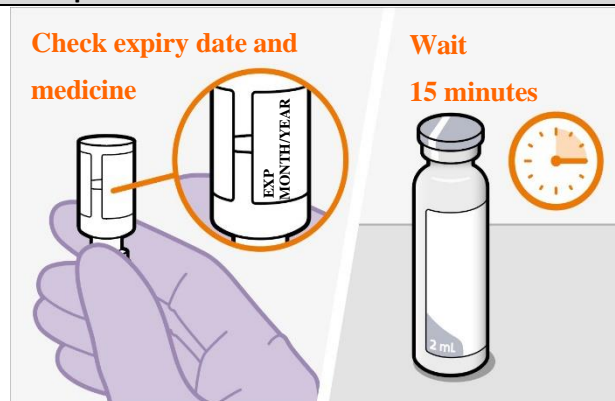
You will also need

- Non-sterile gloves
- 2 alcohol swabs
- 2 gauze pads
- A suitable sharps container

Make sure to have the cabotegravir 2 mL package also available before starting.

Preparation

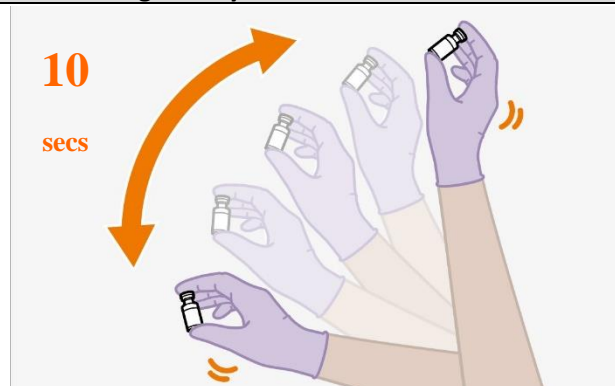
1. Inspect vial



- Check that the expiry date has not passed.
- Inspect the vial immediately. If you can see foreign matter, do not use the product.
- Wait at least 15 minutes before you are ready to give the injection to allow the medicine to come to room temperature.

Do not use if the expiry date has passed.

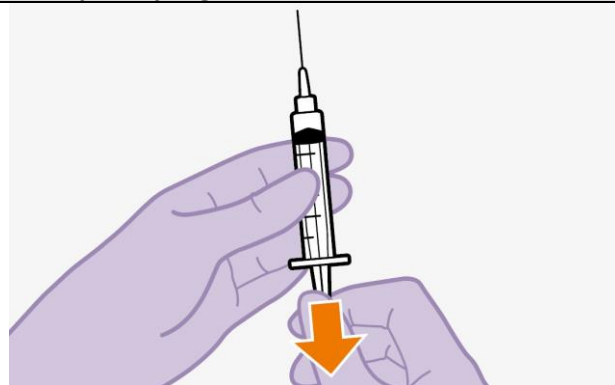
2. Shake vigorously



- 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.
- 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.

3. Prepare syringe and needle



- Attach the aspiration needle to the syringe.
- Use the aspiration needle to perforate the rubber stopper of the vial.
- It is recommended that you inject 1 mL of air into the vial to allow the required volume to be drawn off.
- If using an aspiration device, follow device instructions to prepare the injection.

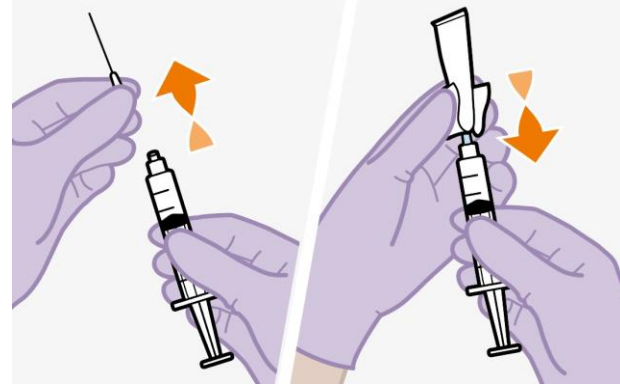
4. Slowly draw up dose



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

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

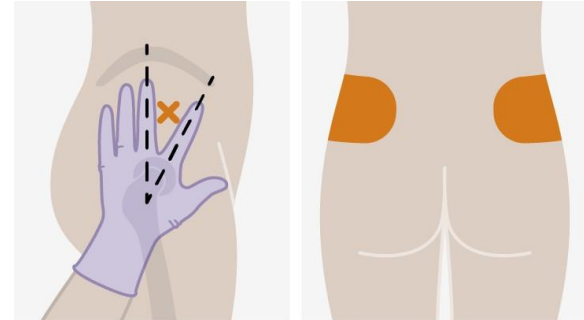
5. Attach injection needle



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

Injection

6. Prepare injection site



Ventrogluteal

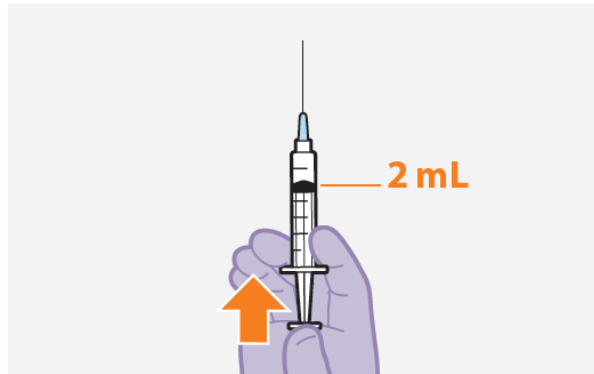
Dorsogluteal

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.

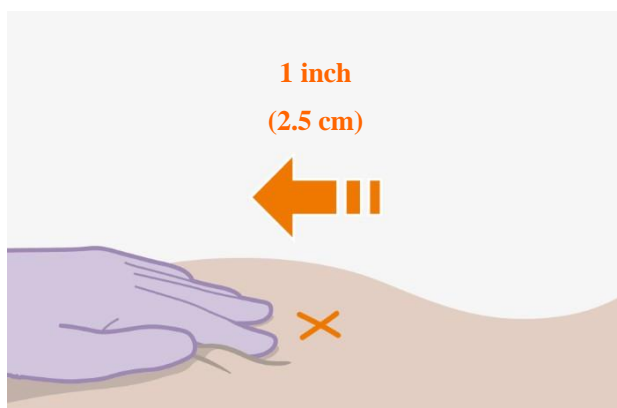
7. Remove extra liquid



- Pull off the injection needle cap.
- Hold the syringe with the needle pointing up. Press the plunger to the 2 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.

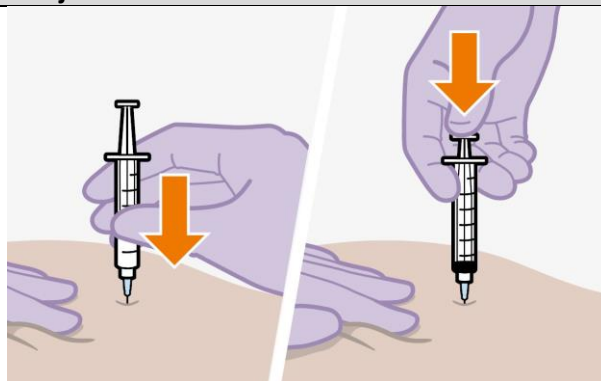
8. Stretch skin



Use the z-track injection technique to minimize medicine leakage from the injection site.

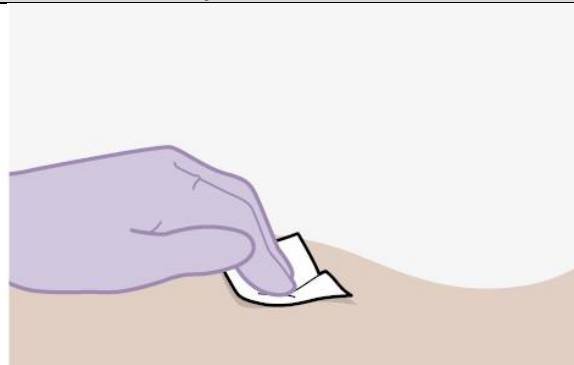
- Firmly drag the skin covering the injection site, displacing it by about an inch (2.5 cm).
- Keep it held in this position for the injection.

9. Inject dose




- Insert the needle to its full depth, or deep enough to reach the muscle.
- Still holding the skin stretched – slowly press the plunger all the way down.
- Ensure the syringe is empty.
- Withdraw the needle and release the stretched skin immediately.

10. Assess the injection site



- Apply pressure to the injection site using a gauze.
- A small bandage may be used if a bleed occurs.
- Dispose of used needles, syringes, and vials according to local health and safety laws.

Do not massage the area.

Repeat for 2nd medicine	
 <p>Repeat all steps for 2nd medicine</p>	<p>If you have not yet injected both medicines, use the steps for preparation and injection for cabotegravir which has its own specific Instructions for Use.</p>
Questions and Answers	
<p>1. How long can the medicine be left out of the refrigerator?</p> <p>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. If not used after 6 hours, it must be discarded.</p> <p>2. How long can the medicine be left in the syringe?</p> <p>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.</p> <p>If 2 hours are exceeded, the filled syringe and needle must be discarded.</p> <p>3. Why do I need to inject air into the vial?</p> <p>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.</p> <p>4. Does the order in which I give the medicines matter?</p> <p>No, the order is unimportant.</p> <p>5. After the package has been stored in the fridge, is it safe to warm the vial up to room temperature more quickly?</p> <p>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.</p> <p>Do not use any other heating methods.</p> <p>6. Why is the ventrogluteal administration approach recommended?</p> <p>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.</p>	

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Date of Revision: 24 November 2022
IFU issued date: 11 March 2021