



## 4. CLINICAL PARTICULARS

### 4.2 Posology and method of administration

#### Method of administration

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REKAMBYS should be administered by a healthcare professional. For instructions on administration, see "Instructions for Use" in the package leaflet. **These instructions should be carefully followed when preparing the suspension for injection to avoid leakage.**

העדכונים העיקריים בעלון **Instructions for Use** הינם:

#### REKAMBYS 2 mL injection Instructions for Use:

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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 (Summary of Product Characteristics).

#### REKAMBYS 2 mL injection Instructions for Use:

##### Overview

A complete dose requires two injections:  
2 mL of cabotegravir and 2 mL of rilpivirine.

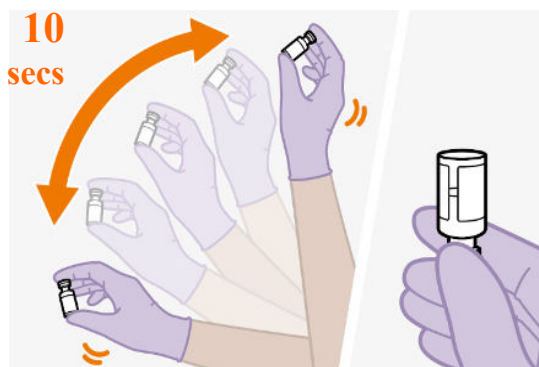
Cabotegravir and rilpivirine are suspensions that do not need further dilution or reconstitution. The preparation steps for both medicines are the same. **Carefully follow these instructions when preparing the suspension for injection to avoid leakage.**

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

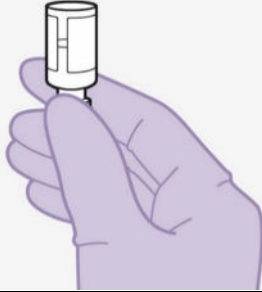
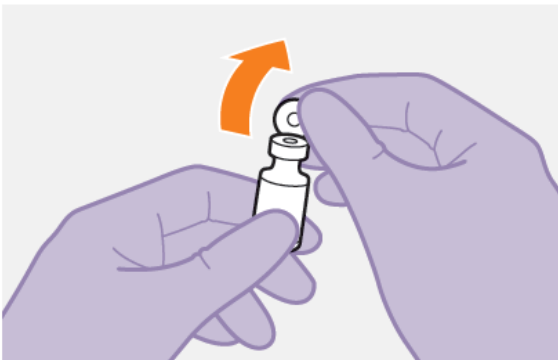
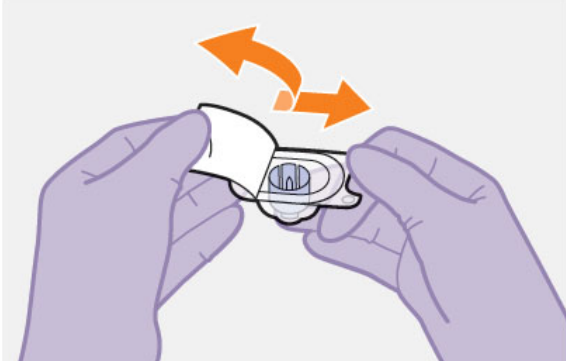
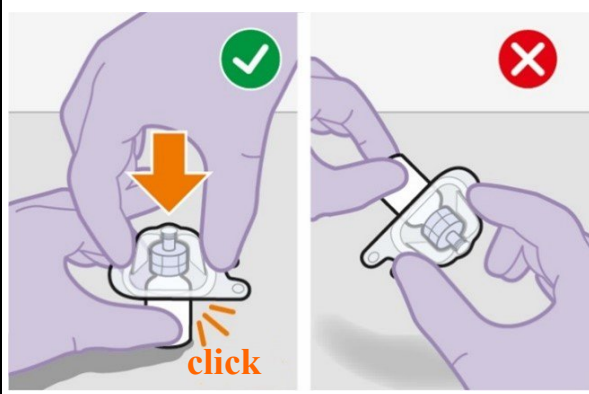
**Note:** The ventrogluteal site is recommended. **The administration order is not important.**


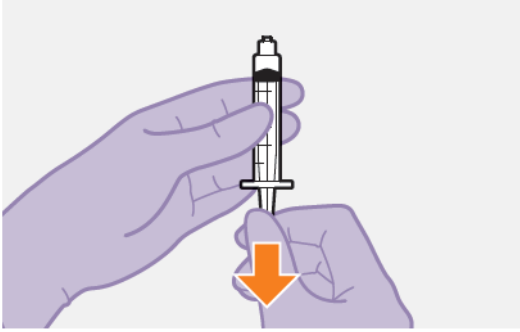
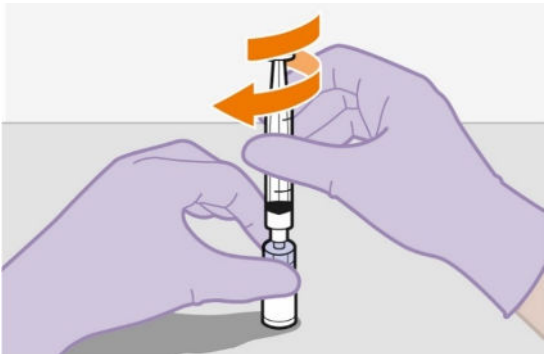
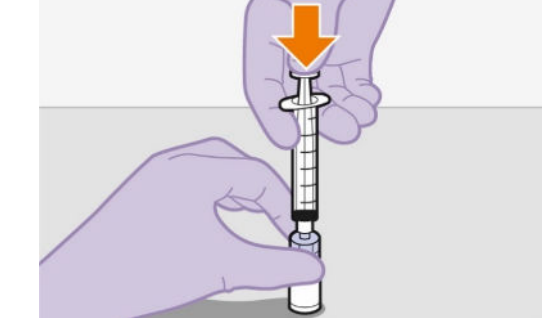
##### Preparation

### 3. Shake vigorously

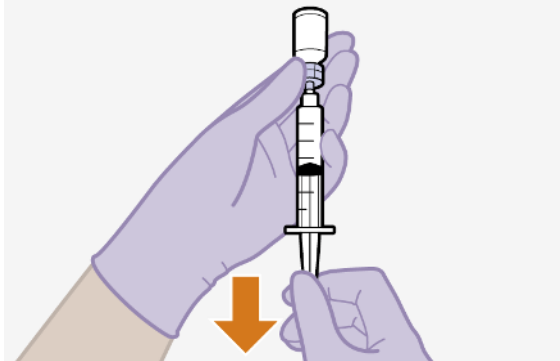


- Hold the vial firmly and vigorously shake for a full 10 seconds as shown.
- **Invert the vial and check the resuspension. It should look uniform. If the suspension is not uniform, shake the vial again. It is also normal to see small air bubbles.**

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| <b>4. Inspect suspension</b>  |  |
|    | <ul style="list-style-type: none"> <li>• Invert the vial and check the resuspension. It should look uniform. If the suspension is not uniform, shake the vial again.</li> <li>• It is also normal to see small air bubbles.</li> </ul> <p><b>Note:</b> Vial preparation order is not important.</p>                  |
| <b>5. Remove vial cap</b>   |  |
|   | <ul style="list-style-type: none"> <li>• Remove the cap from the vial.</li> <li>• Wipe the rubber stopper with an alcohol swab.</li> </ul> <p><b>Do not</b> allow anything to touch the rubber stopper after wiping it.</p>  |
| <b>6. Peel open vial adaptor</b>  |  |
|  | <ul style="list-style-type: none"> <li>• Peel off the paper backing from the vial adaptor packaging.</li> </ul> <p><b>Note:</b> Do not <del>keep</del> remove the adaptor from its <del>in place in</del> packaging for the next step. The adaptor will not fall out when the packaging is turned upside down.</p>   |
| <b>7. Attach vial adaptor</b>   |  |
|  | <ul style="list-style-type: none"> <li>• Place the vial on a flat surface.</li> <li>• Press the vial adaptor straight down onto the vial, using the packaging, as shown. The vial adaptor should <b>snap click</b> securely into place. When you are ready, lift off the vial adaptor packaging as shown.</li> </ul> |

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| <b>8. Lift off the packaging</b>  |   |
|    | <ul style="list-style-type: none"> <li>Lift off the vial adaptor packaging, as shown.</li> </ul>  |
| <b>9. Prepare syringe</b>   |   |
|   | <ul style="list-style-type: none"> <li>Remove the syringe from its packaging.</li> <li>Draw 1 mL of air into the syringe. This will make it easier to draw up the liquid later.</li> </ul>  |
| <b>10 Attach syringe</b>  |   |
|  | <ul style="list-style-type: none"> <li>Hold the vial adaptor and vial firmly, as shown.</li> <li>Screw the syringe firmly onto the vial adaptor.</li> <li><del>Press the plunger all the way down to push the air into the vial.</del></li> </ul> |
| <b>11. Press the plunger</b>  |   |
|  | <p>Press the plunger all the way down to push the air into the vial.</p>  |

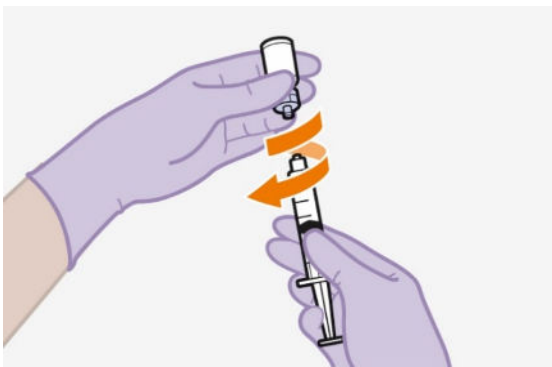
### 12. Slowly draw up dose



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

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

### 13. Unscrew syringe



- Hold the syringe plunger firmly in place as shown to prevent leakage. It is normal to feel some back pressure.
- Screw the syringe off the vial adaptor, holding the vial adaptor as shown.

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

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### Repeat for 2nd medicine



If you have not yet injected cabotegravir follow its own specific instructions for use for preparation and injection of the medicine. **both medicines, use the steps for preparation and injection for Cabotegravir which has its own specific Instructions for Use.**

**REKAMBYS 3 mL injection Instructions for Use:**

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 (Summary of Product Characteristics).

**REKAMBYS 3 mL injection Instructions for Use:**

**Overview**

A complete dose requires two injections:  
3 mL of cabotegravir and 3 mL of rilpivirine.

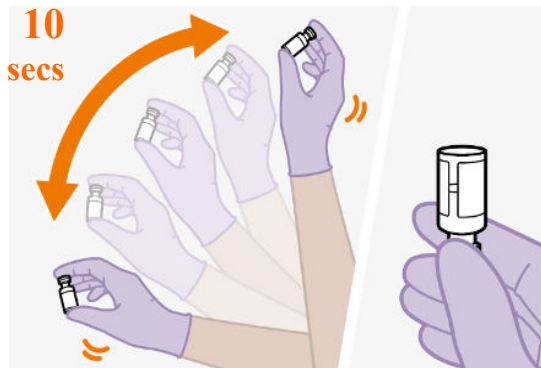
Cabotegravir and rilpivirine are suspensions that do not need further dilution or reconstitution. The preparation steps for both medicines are the same. **Carefully follow these instructions when preparing the suspension for injection to avoid leakage.**

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

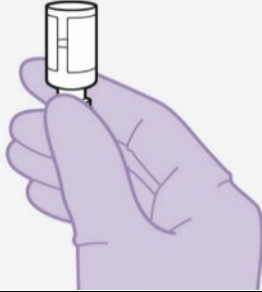
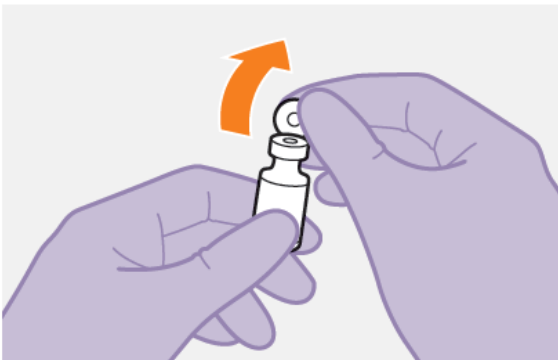
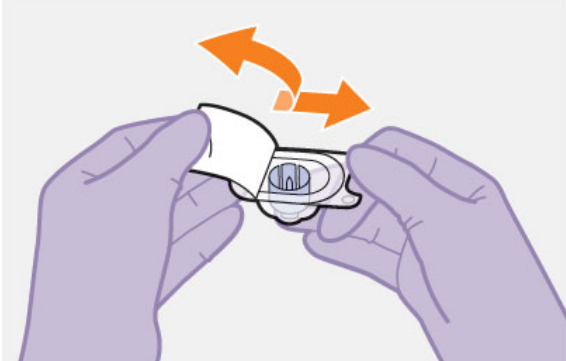
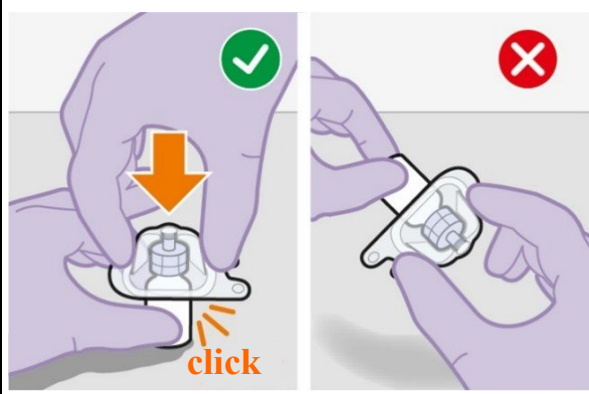
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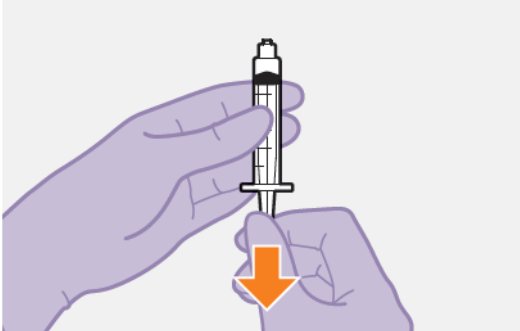
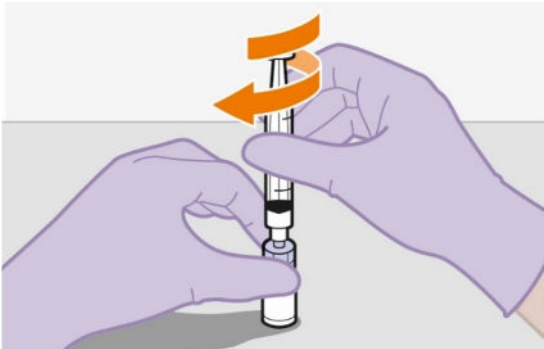
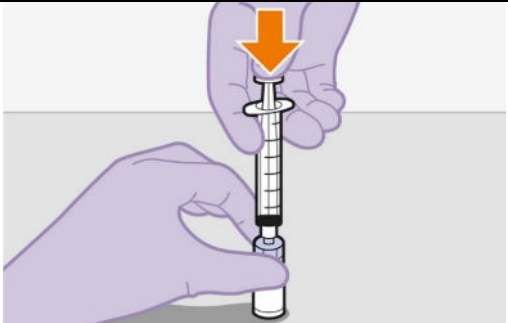
**Preparation**

**3. Shake vigorously**



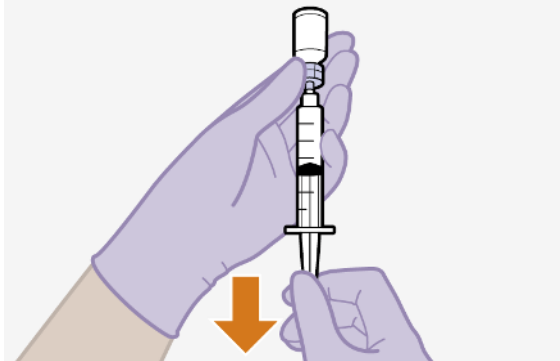
- Hold the vial firmly and vigorously shake for a full 10 seconds as shown.
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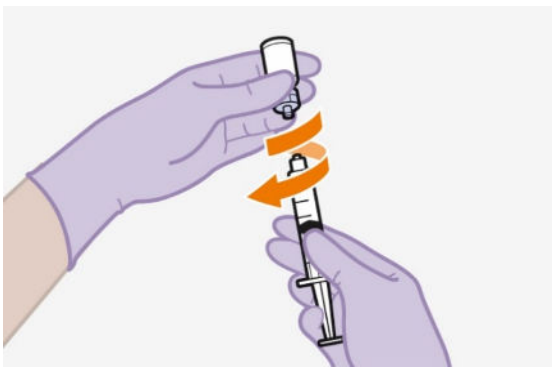
### 12. Slowly draw up dose



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

### 13. Unscrew syringe



- Hold the syringe plunger firmly in place as shown to prevent leakage. It is normal to feel some back pressure.
- Screw the syringe off the vial adaptor, holding the vial adaptor as shown.

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

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### After injection

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### Repeat for 2nd medicine



If you have not yet injected cabotegravir follow its own specific instructions for use for preparation and injection of the medicine. ~~both medicines, use the steps for preparation and injection for Cabotegravir which has its own specific Instructions for Use.~~