

הנדון: ווקבריה זריקה Vocabria Injection

רופא/ה נכבד/ה,
רוקח/ת נכבד/ה,

חברת גלקסוסמיטקליין ישראל בע"מ (GSK) מבקשת להודיע על עדכון העלונים לרופא ולצרכן של התכשיר **Vocabria Injection**.

בהודעה זו כלולים השינויים המהותיים בעלון לרופא ובעלון לצרכן.

מרכיב פעיל וחוזקו:

Cabotegravir – 200mg/ml

התוויה הרשומה לתכשיר בישראל:

Vocabria injection is indicated, in combination with rilpivirine injection, for the treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen without present or past evidence of viral resistance to, and no prior virological failure with agents of the NNRTI and INI class.

עדכונים מהותיים נעשו בסעיפים הבאים בעלון לרופא: 

4.2 Posology and method of administration

Method of administration

For intramuscular use. Care should be taken to avoid inadvertent injection into a blood vessel.

Vocabria injection should be administered by a healthcare professional. For instructions on administration, see "Instructions for Use" in the package leaflet. Carefully follow these instructions when preparing the suspension for injection to avoid leakage.

עדכונים הבאים נעשו בפרק - Instructions for use בעלונים לרופא ולצרכן: 

במכתב זה מוצגים העדכונים שנעשו עבור הוראות השימוש של ויאל 3 מ"ל בלבד – מודגש שעדכונים זהים בוצעו גם בהוראות השימוש עבור ויאל 2 מ"ל.

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. 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 gluteal sites. ~~The administration order is not important.~~

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



Storage information

• Do not store above 30°C.

Do not freeze.

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.

Cabotegravir vial

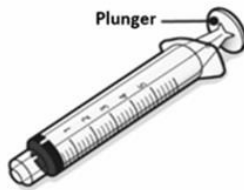


Vial cap
(Rubber stopper under cap)

Vial adaptor

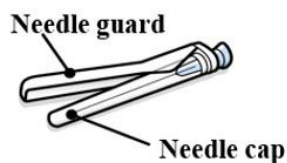


Syringe



Plunger

Injection needle



Needle guard

Needle cap

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.

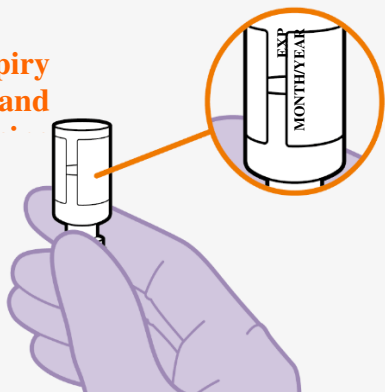
+ 1 rilpivirine 3-mL pack



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.

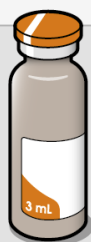
Note: The cabotegravir vial has a brown tint to the glass.

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.

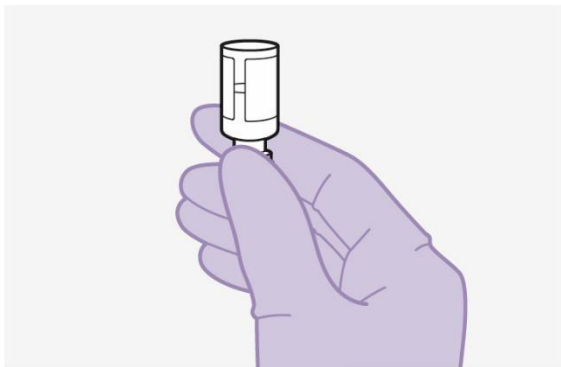
3. Shake vigorously

10 secs



- Hold the vial firmly and vigorously shake for a full 10 seconds as shown.

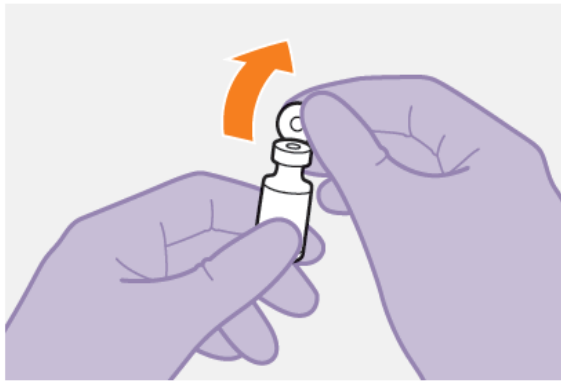
4. Inspect suspension



- ~~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.

Note: Vial preparation order is not important

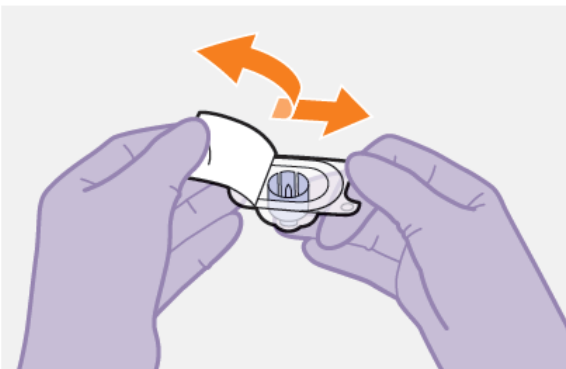
54. Remove vial cap



- 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.

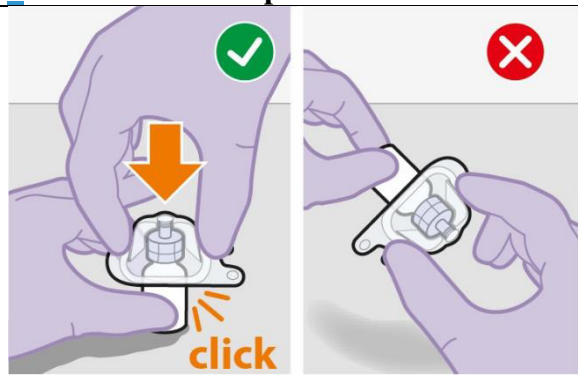
65. Peel open vial adaptor



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

Note: ~~Keep~~ Do not remove the adaptor in place in from its packaging for the next step. The adaptor will not fall out when its packaging is turned upside down.

76. Attach vial adaptor



- Place the vial on a flat surface.
- Press the vial adaptor straight down onto the vial ~~using the packaging~~, as shown.
- The vial adaptor should ~~snap~~click securely into place.

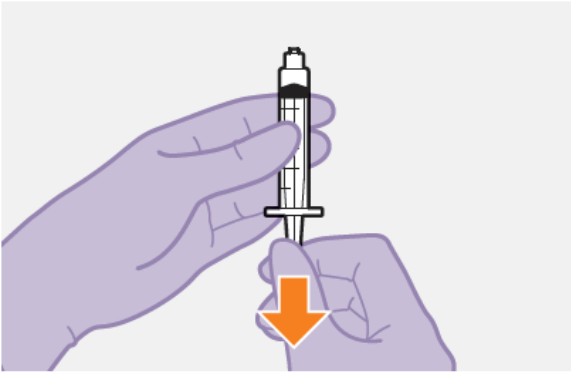
~~When you are ready, lift off the vial adaptor packaging as shown.~~

8. Lift off the packaging



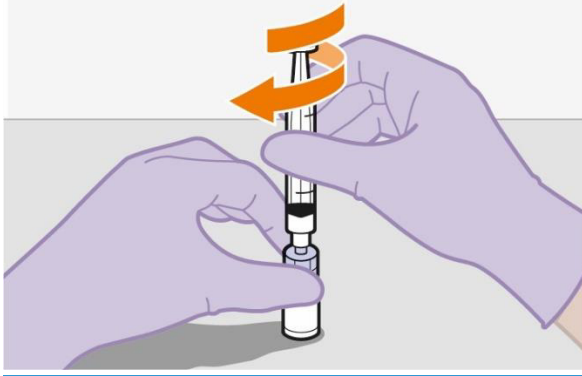
- Lift off the vial adaptor packaging, as shown.

97. Prepare syringe



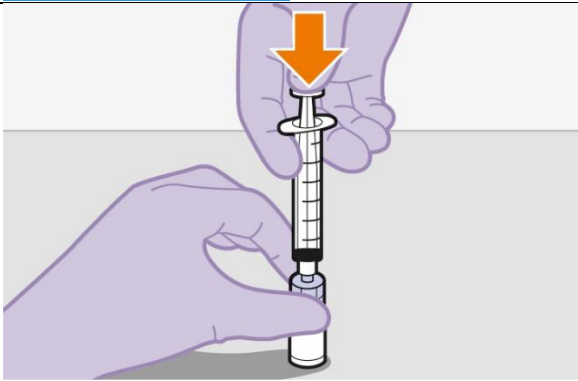
- Remove the syringe from its packaging.
- Draw 1 mL of air into the syringe. This will make it easier to draw up the liquid later.

108. Attach syringe



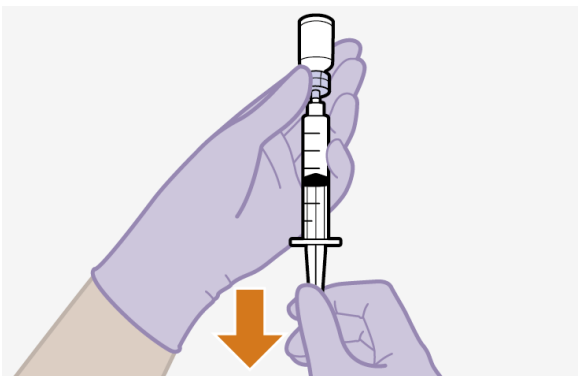
- Hold the vial adaptor and vial firmly, as shown.
- Screw the syringe firmly onto the vial adaptor.
 - ~~Press the plunger all the way down to push the air into the vial.~~

11. Press the plunger



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

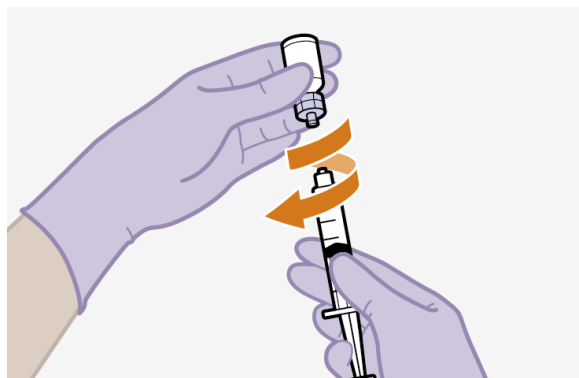
129. Slowly draw up dose



- 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.

Note: Keep the syringe upright to avoid leakage.

1340. Unscrew syringe

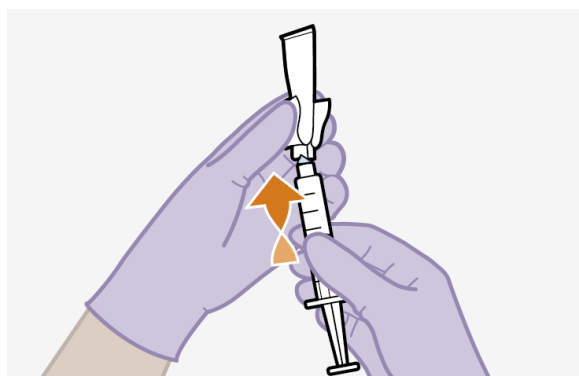


- Hold the syringe plunger firmly in place as shown to prevent leakage. It is normal to feel some back pressure.
- Screw the syringe off the vial adaptor, holding the vial adaptor as shown.

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

Note: Check that the cabotegravir suspension looks uniform and white to light pink.

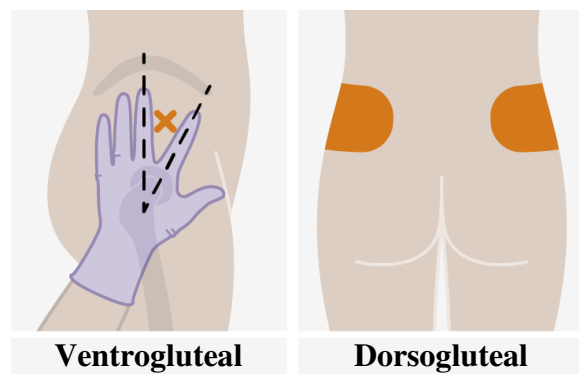
1411. Attach needle



- 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

1512. Prepare injection site



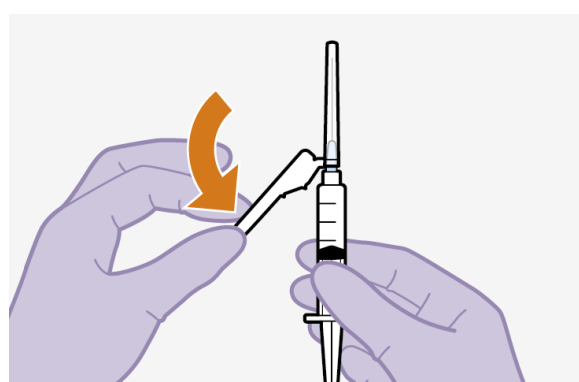
Injections must be administered to the gluteal sites.

Select from the following areas for the injection:

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

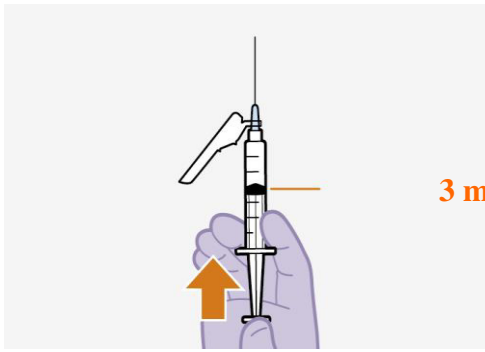
Note: For gluteal intramuscular use only. **Do not** inject intravenously.

1613. Remove cap



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

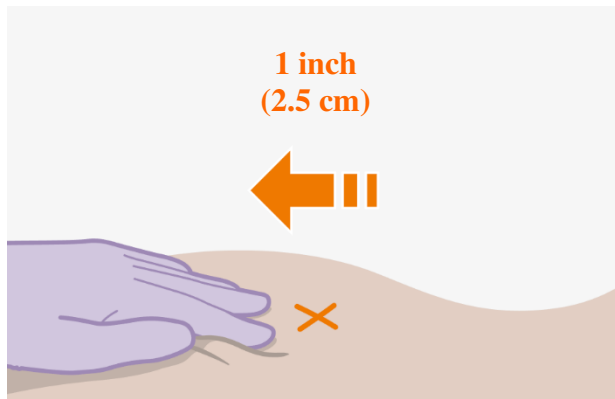
1714. Remove extra liquid



- 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.

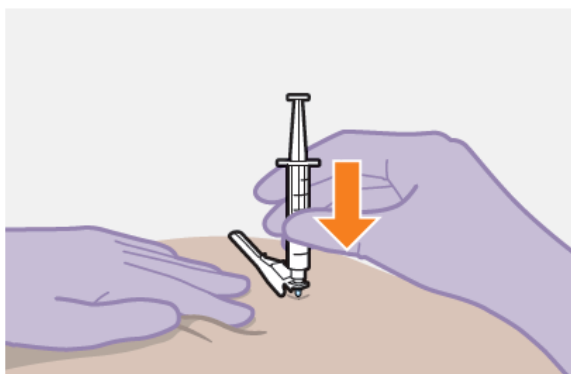
1815. Stretch skin



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

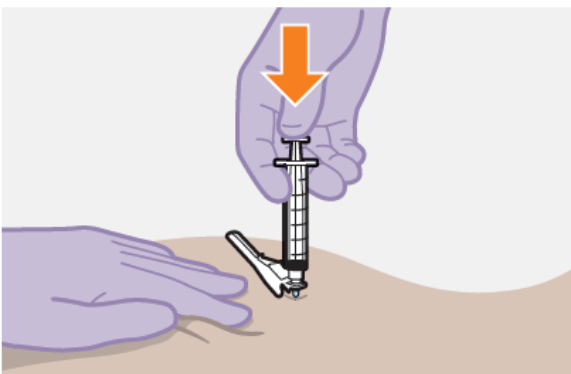
- Firmly drag the skin covering the injection site, displacing it by about an inch (2.5 cm).
- Keep it held in this position for the injection.

1619. Insert needle



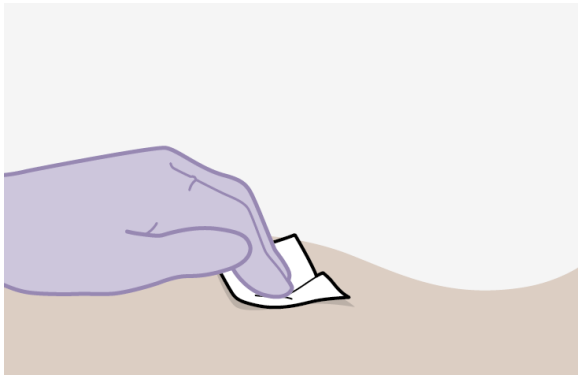
- Insert the needle to its full depth, or deep enough to reach the muscle.

1720. Inject dose



- 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.

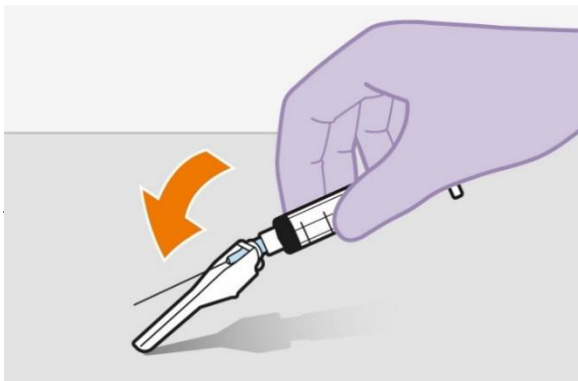
1821. Assess the injection site



- Apply pressure to the injection site using a gauze.
- A small bandage may be used if a bleed occurs.

Do not massage the area.

1922. Make needle safe

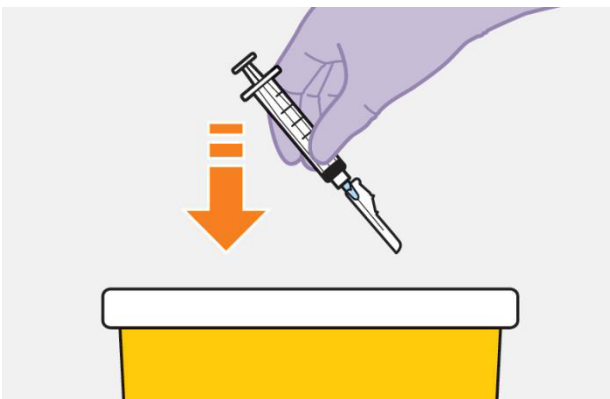


- Fold the needle guard over the needle.
- Gently apply pressure using a hard surface to lock the needle guard in place.
- The needle guard will make a click when it locks.



After injection

2320. Dispose safely



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

Repeat for 2nd medicine



**Repeat all steps
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.

מקרא לעדכונים המסומנים :

מידע שהוסר – מסומן בקו אדום חוצה ~~XXX~~

תוספת – כתב **כחול**

תוספת החמרה - כתב **כחול** – מסומן בצהוב מרקר

העלונים לרופא ולצרכן נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות:
<https://data.health.gov.il/drugs/index.html#/byDrug> וניתן לקבלם מודפסים על-ידי פניה לחברת גלקסוסמייתקליין רח' בזל
25 פתח תקוה בטלפון: 03-9297100.

בברכה,
טניה רשקובן
רוקחת ממונה