



נובמבר 2022

הנדון: VARILRIX / ורילריקס
Varicella Vaccine
Powder and solvent for solution for injection
הודעה על עידכון העלון לרופא ולצרכן

רופא/ה נכבד/ה
רוקח/ת נכבד/ה,

חברת גלקסוסימיתקליין ישראל בע"מ (GSK) מבקשת להודיע על עדכון העלון לרופא ולצרכן של התכשיר ורילריקס/Varilrix.

חומר פעיל:

LIVE ATTENUATED VARICELLA VIRUS NLT 10^{3.3} plaque forming Units (PFU)

ההתוויה הרשומה לתכשיר בישראל:

Varilrix is intended for the active immunization against varicella of the categories of persons listed below, where there is no history of varicella.

- Healthy subjects, from the age of 12 months.
- Patients at high risk of severe varicella, such as patients with acute leukemia or a chronic condition, those on immunosuppressive therapy or those for whom an organ transplant is being considered.
- Healthy persons living in close contact with patients with varicella and high-risk patients.

בהודעה זו מצויינים השינויים המהותיים שבוצעו לעלונים.

מקרא לעדכונים המסומנים:

תוספת – כתב כחול

מחיקה-כתב אדום עם קו מחיקה

להלן העידכונים שנעשו בעלון לרופא:

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

~~Varilrix is a lyophilized preparation of the live attenuated varicella virus (OKA strain) produced in human diploid cell cultures.~~

~~Each 0.5 ml dose of reconstituted vaccine contains not less than 10^{3.3} plaque forming units (PFU).~~

After reconstitution, one dose (0.5 mL) contains:

Varicella virus¹ Oka strain (live, attenuated) not less than 10^{3.3} PFU²

¹ produced in human diploid cells (MRC-5)

² plaque forming units

This vaccine contains a trace amount of neomycin. (See section 4.3).

Excipients with known effect:

The vaccine contains 6 mg of sorbitol per dose, see section 4.3.

The vaccine contains 331 micrograms of phenylalanine per dose (see section 4.4).

For the full list of excipients, see section 6.1.

4.4 Special warnings and precautions for use

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Phenylalanine content

The vaccine contains 331 micrograms of phenylalanine per dose. Phenylalanine may be harmful for individuals with phenylketonuria (PKU).

6.4 Special precautions for storage

Store in a refrigerator (2°C –to 8°C).

Store in the original package in order to protect from light.

~~The use by date is the last day of the month printed on the pack after the letters EXP.~~

For storage conditions after reconstitution of the medicinal product, see section 6.3.

Instructions for reconstitution of the vaccine with solvent presented in ampoules

The solvent and the reconstituted vaccine should be inspected visually for any foreign particulate matter and/or abnormal physical appearance before administration. In the event of either being observed, do not administer the vaccine.

The vaccine must be reconstituted by adding the entire contents of the supplied ampoule of solvent to the vial containing the powder. The mixture should be well shaken until the powder is completely dissolved in the solvent.

The colour of the reconstituted vaccine may vary from clear peach to pink due to minor variations of its pH. This is normal and does not impair the performance of the vaccine. In the event of other variation being observed, do not administer the vaccine.

Withdraw the entire contents of the vial.

A new needle should be used to administer the vaccine.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements. VARILRIX must be reconstituted by adding the entire contents of the supplied ampoule of solvent to the vial containing the powder. The mixture should be shaken well until the powder is completely dissolved in the solvent.

~~The vaccine should be used promptly after reconstitution.~~

~~Withdraw the entire contents of the vial.~~

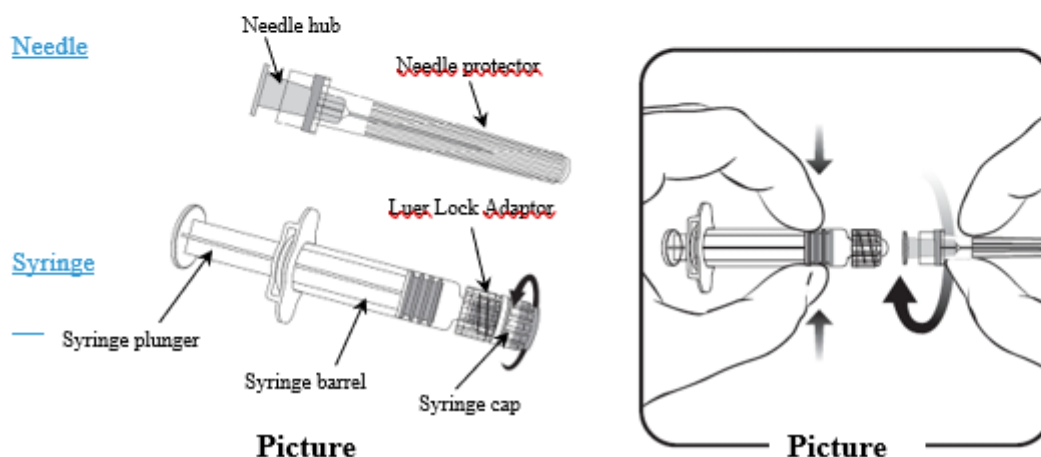
~~A new needle should be used to administer the vaccine.~~

Instructions for reconstitution of the vaccine with solvent presented in a pre-filled syringe

The solvent and the reconstituted vaccine should be inspected visually for any foreign particulate matter and/or abnormal physical appearance before administration. In the event of either being observed, do not administer the vaccine.

The vaccine must be reconstituted by adding the entire contents of the pre-filled syringe of solvent to the vial containing the powder.

To attach the needle to the syringe, carefully read the instructions given with pictures 1 and 2. However, the syringe provided with Varilrix might be slightly different (without screw thread) than the syringe illustrated. In that case, the needle should be attached without screwing.



Always hold the syringe by the barrel, not by the syringe plunger or the Luer Lock Adaptor (LLA) and maintain the needle in the axis of the syringe (as illustrated in picture 2). Failure to do this may cause the LLA to become distorted and leak.

During assembly of the syringe, if the LLA comes off, a new vaccine dose (new syringe and vial) should be used.

1. Unscrew the syringe cap by twisting it anticlockwise (as illustrated in picture 1).

Whether the LLA is rotating or not, please follow the below steps:

2. Attach the needle to the syringe by gently connecting the needle hub into the LLA and rotate a quarter turn clockwise until you feel it lock (as illustrated in picture 2).

3. Remove the needle protector, which may be stiff.

4. Add the solvent to the powder. The mixture should be well shaken until the powder is completely dissolved in the solvent.

The colour of the reconstituted vaccine may vary from clear peach to pink due to minor variations of its pH. This is normal and does not impair the performance of the vaccine. In the event of other variation being observed, do not administer the vaccine.

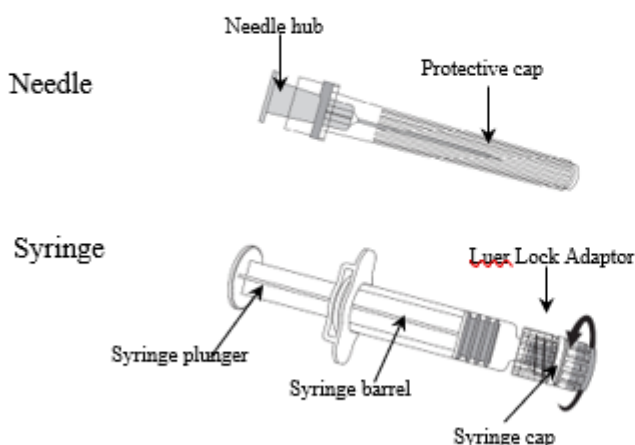
5. Withdraw the entire contents of the vial.

6. A new needle should be used to administer the vaccine. Unscrew the needle from the syringe and attach the injection needle by repeating step 2 above.

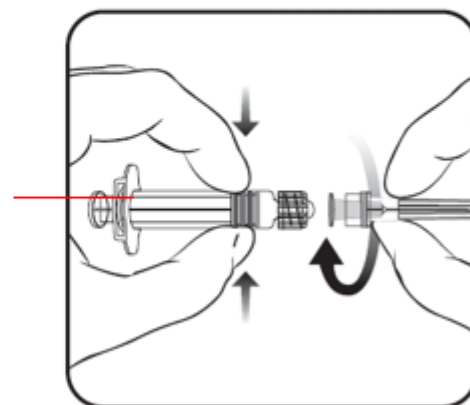
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

~~VARILRIX must be reconstituted by adding the entire contents of the pre-filled syringe containing the solvent to the vial containing the powder.~~

~~To attach the needle to the syringe, please read carefully the instructions in the Figures 1 and 2. However, the syringe provided with VARILRIX might be slightly different (without screw head) from the syringe described in the drawing. In that case, the needle should be attached without screwing.~~



Picture 1



Picture 2

~~-Always hold the syringe by the barrel, not the plunger or the Luer Lock adapter (LLA), and keep the needle in line with the syringe (see Figure 2). Failure to comply with this instruction could cause deformation or leakage of the LLA.~~

~~When assembling the syringe, if the LLA comes off, a new dose of the vaccine (new syringe and new vial) should be used~~

- ~~1. Unscrew the syringe cap by twisting it counterclockwise (see Figure 1).
Whether the LLA is twisting or not, please follow the steps below:~~
- ~~2. Attach the needle to the syringe by carefully placing the needle hub in the LLA and twisting it a quarter of a turn in a clockwise direction until you feel it is blocked (see Figure 2).~~
- ~~3. Remove the protective cap from the needle, which could be a little difficult.~~
- ~~4. Add the solvent to the powder. The mixture should be shaken well until the powder is completely dissolved in the solvent.~~

~~The vaccine should be used promptly after reconstitution.~~

~~5. Withdraw the entire content of the vial.~~

~~6. A new needle should be used to administer the vaccine. Unscrew the needle from the syringe and attach the needle for injection by repeating step 2 above.~~

~~Any unused medicinal product or waste material should be disposed of in accordance with local requirements.~~

להלן העידכונים שנעשו בעלון לצרכן:

מידע חשוב על חלק מהמרכיבים של התרופה

ורילריקס מכיל סורביטול ופנילאליני

התכשיר מכיל 6 מ"ג סורביטול בכל מנה.

התכשיר מכיל 331 מיקרוגרם של פניאלנין בכל מנה.

פנילאליני עלול להזיק אם יש לך פנילקטומריה (PKU). הפרעה גנטית נדירה שבה פנילאליני

מצטבר מאחר שהגוף לא יכול לסלק אותו כראוי.

5. איך לאחסן את התרופה?

- מנע הרעלה! תרופה זו וכל תרופה אחרת יש לשמור במקום סגור מחוץ להישג ידם וטווח ראייתם של ילדים ו/או תינוקות ועל ידי כך תמנע הרעלה. אל תגרום להקאה ללא הוראה מפורשת מהרופא.
 - אין להשתמש בתרופה אחרי תאריך התפוגה (exp. date) המופיע על גבי האריזה. תאריך התפוגה מתייחס ליום האחרון של אותו חודש.
 - יש לאחסן במקרר (בין 2°C ל-8°C).
 - יש לאחסן באריזה המקורית על מנת להגן מפני אור.
 - לאחר הכנה, יש להזריק את החיסון **בהקדם האפשרי באופן מיידי**.
- אם הדבר אינו אפשרי, אולם הודגם כי ניתן לאחסן את החיסון המוכן עד ל-90 דקות בטמפרטורת החדר (25°C) עד או עד 8 שעות במקרר (בין 2°C ל-8°C). אם לא משתמשים בחיסון המוכן במסגרת תנאי איחסון אלה וזמנים אלה, יש לזרוק אותו.**

- אין להשליך תרופות לביוב או לפסולת הביתית. התייעץ עם הרוקח כיצד לזרוק תרופות שאינן בשימוש. צעדים אלו יסייעו להגנה על הסביבה.

The following information is intended for healthcare professionals only:

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following the administration of the vaccine.

Alcohol and other disinfecting agents must be allowed to evaporate from the skin before injection of the vaccine since they can inactivate the attenuated viruses in the vaccine.

Varilrix must not be administered intravascularly or intradermally.

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products

Instructions for reconstitution of the vaccine with solvent presented in ampoules

The solvent and the reconstituted vaccine should be inspected visually for any foreign particulate matter and/or abnormal physical appearance before administration. In the event of either being observed, do not administer the vaccine.

The vaccine must be reconstituted by adding the entire contents of the supplied ampoule of solvent to the vial containing the powder. The mixture should be well shaken until the powder is completely dissolved in the solvent. The colour of the reconstituted vaccine may vary from clear peach to pink due to minor variations of its pH. This is normal and does not impair the performance of the vaccine. In the event of other variation being observed, do not administer the vaccine.

Withdraw the entire contents of the vial.

A new needle should be used to administer the vaccine.

After reconstitution, it is recommended that the vaccine be injected as soon as possible.

However, it has been demonstrated that the reconstituted vaccine may be kept for up to 90 minutes at room temperature (25°C) and up to 8 hours in the refrigerator (2°C to 8°C). If not used within the recommended in-use storage timeframes and conditions, the reconstituted vaccine must be discarded.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

~~VARILRIX must be reconstituted by adding the entire contents of the supplied ampoule of solvent to the vial containing the powder. The mixture should be shaken well until the powder is completely dissolved in the solvent. The vaccine should be used promptly after reconstitution.~~

~~Withdraw the entire contents of the vial.~~

~~A new needle should be used to administer the vaccine.~~

Instructions for reconstitution of the vaccine with solvent presented in a pre-filled syringe

The solvent and the reconstituted vaccine should be inspected visually for any foreign particulate matter and/or abnormal physical appearance before administration. In the event of either being observed, do not administer the vaccine.

The vaccine must be reconstituted by adding the entire contents of the pre-filled syringe of solvent to the vial containing the powder.

To attach the needle to the syringe, carefully read the instructions given with pictures 1 and 2. However, the syringe provided with Varilrix might be slightly different (without screw thread) than the syringe illustrated.

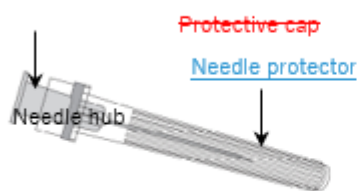
In that case, the needle should be attached without screwing.

~~VARILRIX must be reconstituted by adding the entire contents of the pre-filled syringe containing the solvent to the vial containing the powder.~~

~~To attach the needle to the syringe, please read carefully the instructions in Figures 1 and 2.~~

~~However, the syringe provided with VARILRIX might be slightly different (without screw head) from the syringe described in the drawing. In that case, the needle should be attached without screwing.~~

Needle



Syringe

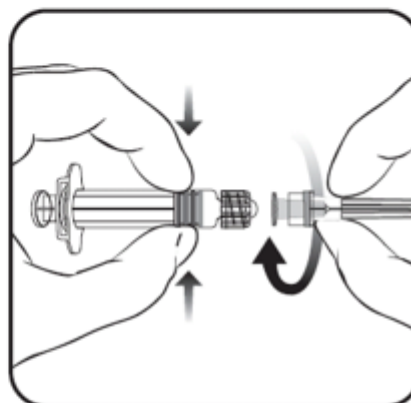
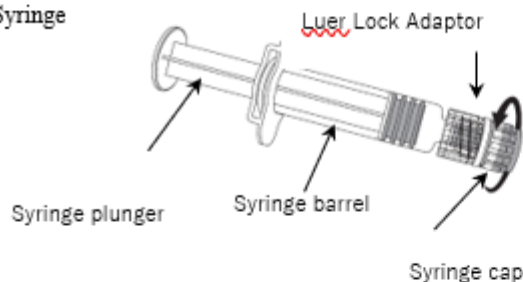


Figure-Picture 1

Picture Figure 2

Always hold the syringe by the barrel, not by the syringe plunger or the Luer Lock adaptor. Adaptor (LLA), and maintain the needle in the axis of the syringe (as illustrated in picture 2), and keep the needle in line with the syringe (see Figure 2). Failure to comply with this instruction could cause deformation or leakage of the LLA. Failure to do this may cause the LLA to become distorted and leak.

During assembly of the syringe, if the LLA comes off, a new vaccine dose (new syringe and vial) should be used.
~~When assembling the syringe, if the LLA comes off, a new dose of the vaccine (new syringe and new vial) should be used.~~

1. Unscrew the syringe cap by twisting it anticlockwise (as illustrated in picture 1), ~~counterclockwise (see Figure 1)~~. Whether the LLA is ~~twisting-rotating~~ or not, please follow the below steps below:
2. Attach the needle to the syringe by carefully placing gently connecting the needle hub into the LLA and twisting it rotate a quarter ~~of a turn~~ in a clockwise direction until you feel it ~~is blocked-lock~~ (see Figure as illustrated in picture 2).
3. Remove the needle protector protective cap from the needle, which ~~could be a little difficult~~ may be stiff.
4. Add the solvent to the powder. The mixture should be well shaken ~~well~~ until the powder is completely dissolved in the solvent.

The colour of the reconstituted vaccine may vary from clear peach to pink due to minor variations of its pH. This is normal and does not impair the performance of the vaccine. In the event of other variation being observed, do not administer the vaccine.

~~The vaccine should be used promptly after reconstitution.~~

5. Withdraw the entire contents of the vial.
6. A new needle should be used to administer the vaccine. Unscrew the needle from the syringe and attach the injection needle ~~for injection~~ by repeating step 2 above.

After reconstitution, it is recommended that the vaccine be injected as soon as possible. However, it has been demonstrated that the reconstituted vaccine may be kept for up to 90 minutes at room temperature (25°C) and up to 8 hours in the refrigerator (2°C to 8°C). If not used within the recommended in-use storage timeframes and conditions, the reconstituted vaccine must be discarded.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

קיימים עדכונים נוספים . למידע נוסף יש לעיין בעלון לרופא ולצרכן המעודכנים.

העלונים לצרכן ולרופא מצורפים להודעה זו.

העלונים לרופא ולצרכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות: <https://www.old.health.gov.il/units/pharmacy/trufot/index.asp?safa=h> וניתן לקבלו מודפס על-ידי פניה לחברת גלקסוסמיטקליין רח' בזל 25 פתח תקוה בטלפון: 03-9297100.

בברכה,
ליליאנה בלטר
רוקחת ממונה