



דצמבר 2023

הנדון: פריוריקס / PRIORIX
Powder and solvent for solution for injection

רופא/ה נכבד/ה
רוקח/ת נכבד/ה,

חברת גלקסוסמיטקליין ישראל בע"מ (GSK) מבקשת להודיע על עדכון העלון לרופא של התכשיר
PRIORIX / פריוריקס.

חומרים פעילים:

-LIVE ATTENUATED MUMPS VIRUS	NLT 10 ^{3.7} CCID ₅₀
- LIVE ATTENUATED RUBELLA VIRUS E	NLT 10 ^{3.0} CCID ₅₀
- LIVE ATTENUATED MEASLES VIRUS	NLT 10 ^{3.0} CCID ₅₀

ההתוויה העדכנית המאושרת לתכשיר בישראל:

PRIORIX is indicated for active immunisation of children from the age of 9 months or older, adolescents and adults against measles, mumps and rubella.

בהודעה זו מצויינים השינויים שבוצעו לעלון .
מקרא לעדכונים המסומנים:
תוספת – כתב כחול
מחיקה-כתב אדום עם קו מחיקה

להלן העידכונים שנעשו בעלון לרופא:

6.6 Special precautions for disposal and handling

The solvent and the reconstituted vaccine should be inspected visually for any foreign particulate matter and/or variation of physical aspects prior to reconstitution or administration. In the event of either being observed, do not use the solvent or the reconstituted vaccine.

Solvent in ampoule

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

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

Due to minor variation of its pH, the reconstituted vaccine may vary in colour from clear peach to fuchsia pink without deterioration of the vaccine potency.

Withdraw the entire contents of the vial.

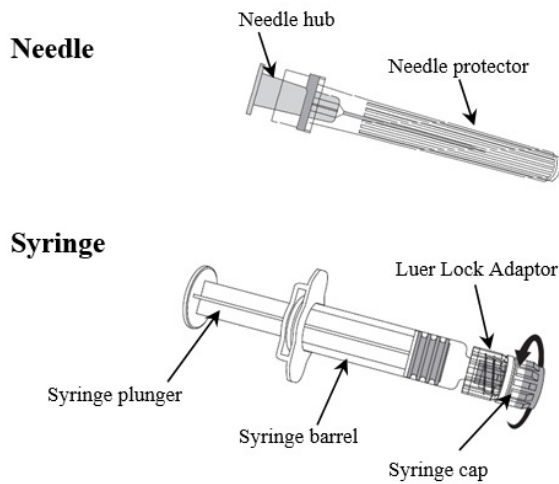
A new needle should be used to administer the vaccine.

Solvent in pre-filled syringe

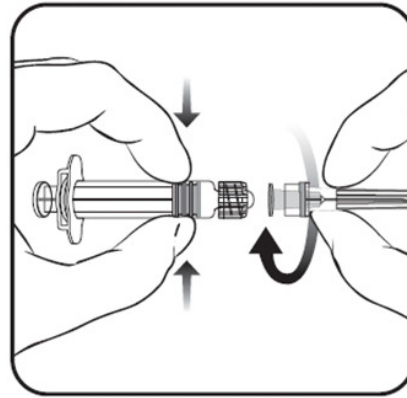
The vaccine must be reconstituted by adding the entire contents of the supplied pre-filled syringe of solvent to the vial containing the powder.

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

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



Picture 1



Picture 2

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.

Due to minor variation of its pH, the reconstituted vaccine may vary in colour from clear peach to fuchsia pink without deterioration of the vaccine potency.

5. Withdraw the entire contents of the vial **and administer it**.
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.

Contacts with disinfectants should be avoided (see section 4.4).

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

למידע נוסף יש לעיין בעלון לרופא המעודן.

העלון לרופא מצורף להודעה זו.

העלון לרופא 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 גלקסוסמיתקליין רח' בזל

25 פתח תקוה בטלפון: 03-9297100.

בברכה,

ליליאנה בלטר
רוקחת ממונה