



ינואר 2020

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

רופא/ה נכבד/ה  
רוקח/ת נכבד/ה,

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

### חומרים פעילים:

-LIVE ATTENUATED MUMPS VIRUS	NLT 10 <sup>3.7</sup> CCID <sub>50</sub>
- LIVE ATTENUATED RUBELLA VIRUS E	NLT 10 <sup>3.0</sup> CCID <sub>50</sub>
- LIVE ATTENUATED MEASLES VIRUS	NLT 10 <sup>3.0</sup> CCID <sub>50</sub>

### ההתוויה העדכנית המאושרת לתכשיר בישראל:

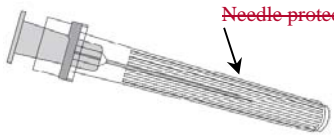
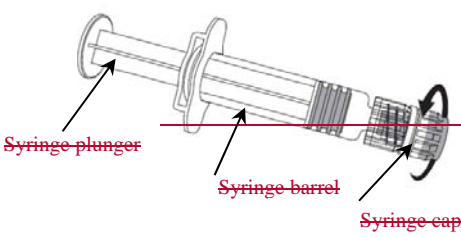
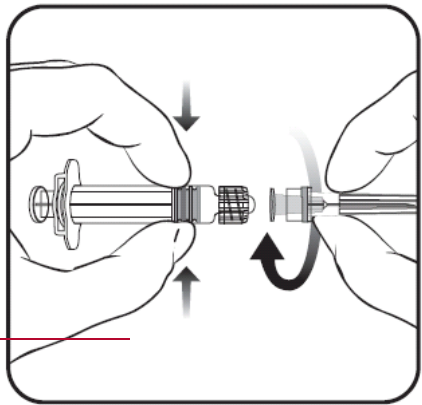
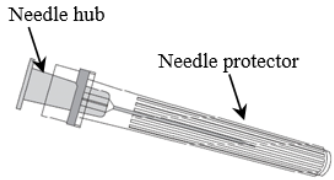
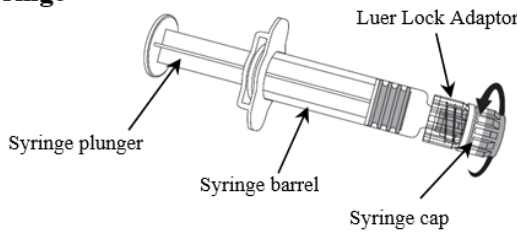
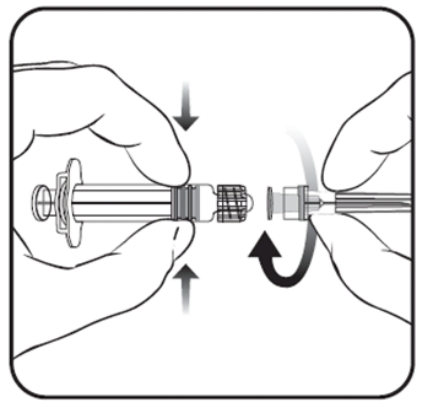
PRIORIX is indicated for active immunisation of children from the age of 9 months or older, adolescents and adults against measles, mumps and rubella.

### בהודעה זו מצויינים השינויים המהותיים שבוצעו לעלון .

מקרא לעדכונים המסומנים:  
תוספת – כתב כחול  
מחיקה-כתב אדום עם קו מחיקה

להלן העידכונים המהותיים שנעשו בעלון לרופא:

Section	Marked update
<b>4.4</b> <b>Special warnings and precautions for use</b>	<p>.....</p> <p><del>Patients with rare hereditary problems of fructose intolerance should not be vaccinated with PRIORIX since it contains sorbitol.</del></p> <p>.....</p>
<b>4.5</b> <b>Interaction with other medicinal products and other forms of interaction</b>	<p><u>Clinical studies have demonstrated that</u> PRIORIX can be given simultaneously <del>(but at separate injection sites)</del> with any of the following monovalent or combination vaccines [including hexavalent vaccines (DTPa-HBV-IPV/Hib)]: diphtheria-tetanus-acellular pertussis vaccine (DTPa), <u>reduced antigen diphtheria-tetanus-acellular pertussis vaccine (dTpa)</u>, <u>Haemophilus influenzae type b vaccine (Hib)</u>, inactivated polio vaccine (IPV), hepatitis B vaccine (HBV), hepatitis A vaccine (HAV), meningococcal <del>serotype-serogroup B vaccine (MenB)</del>, <u>meningococcal serogroup C conjugated-conjugate vaccine (MenC)</u>, <u>meningococcal serogroups A, C, W-135 and Y conjugate vaccine (MenACWY)</u>, varicella zoster vaccine (VZV), oral polio vaccine (OPV) and <del>10-valent</del> pneumococcal conjugate vaccine in accordance with local recommendations.</p> <p><u>Due to an increased risk of fever, tenderness at the injection site, change in eating habits and irritability when Bexsero was co-administered with a combined measles-mumps-rubella-varicella (MMR-V) vaccine, separate vaccination with PRIORIX can be considered when possible.</u></p> <p>.....</p> <p><u>If PRIORIX is to be given at the same time as another injectable vaccine, the vaccines should always be administered at different injection sites.</u></p>

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<b>6.6 Special precautions for disposal and handling</b>	<p>The solvent and <a href="#">the</a> reconstituted vaccine should be inspected visually for any foreign particulate matter and/or variation of physical aspects prior to <a href="#">reconstitution or</a> administration. In the event of either being observed, <del>discard</del> <a href="#">do not use</a> the solvent or <a href="#">the</a> reconstituted vaccine.</p> <p>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.</p> <p>To attach the needle to the syringe, <del>refer to</del> <a href="#">carefully read the below drawing instructions given with pictures 1 and 2</a>. However, the syringe provided with PRIORIX might be slightly different (without screw thread) than the syringe <del>described in the</del> <a href="#">drawing illustrated</a>.</p> <p><a href="#">In that case, the needle should be attached without screwing.</a></p> <div style="display: flex; justify-content: space-around; align-items: flex-start;"> <div style="text-align: center;"> <p><b>Needle</b></p>  <p><b>Syringe</b></p>  </div> <div style="text-align: center;">  </div> </div> <div style="display: flex; justify-content: space-around; align-items: flex-start; margin-top: 20px;"> <div style="text-align: center;"> <p><b>Needle</b></p>  <p><b>Syringe</b></p>  </div> <div style="text-align: center;">  </div> </div> <div style="display: flex; justify-content: space-around; margin-top: 10px;"> <p><b>Picture 1</b></p> <p><b>Picture 2</b></p> </div> <p><a href="#">1. ——— Holding</a> <a href="#">Always hold</a> the syringe <a href="#">by the barrel</a> <del>in one hand (avoid holding , not</del> <a href="#">by the syringe plunger)</a>, <del>unscrew</del> <a href="#">or the Luer Lock Adaptor (LLA)</a>, and <a href="#">maintain the needle in the axis of the syringe (as illustrated in picture 2)</a>. <a href="#">Failure to do this may cause the LLA to become distorted and leak.</a></p>

	<p><u>During assembly of the syringe, if the LLA comes off, a new vaccine dose (new syringe and vial) should be used.</u></p> <p>1. <u>Unscrew</u> the syringe cap by twisting it anticlockwise <u>(as illustrated in picture 1).</u></p> <p><del>2. —To attach</del> <u>Whether the LLA is rotating or not, please follow below steps:</u></p> <p>2. <u>Attach</u> the needle to the syringe, <del>twist by gently connecting</del> the needle <u>hub into the LLA and rotate a quarter turn</u> clockwise <del>into the syringe</del> until you feel it lock (<del>see as</del> <u>illustrated in picture 2).</u></p> <p>3. <u>Remove</u> the needle protector, which <del>on occasion can be a little</del> <u>may be</u> stiff.</p> <p>4. <u>Add</u> the solvent to the powder. <del>After the addition of the solvent to the powder, the</del> <u>The</u> mixture should be well shaken until the powder is completely dissolved in the solvent.</p> <p>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.</p> <p>5. <u>Withdraw</u> the entire contents of the vial and administer it.</p> <p>6. A new needle should be used to administer the vaccine. <u>Unscrew the needle from the syringe and attach the injection needle by repeating step 2 above.</u></p>
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קיימים עדכונים נוספים . למידע נוסף יש לעיין בעלון לרופא המעודכן.  
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