

הנדון: Infanrix IPV- HIB / אינפנריקס אי.פי.וי. איץ.אי.בי**Powder and suspension for suspension for injection**

רופא/ה נכבד/ה

רוקח/ת נכבד/ה,

חברת גלקסוסמיתקליין ישראל בע"מ (GSK) מבקשת להודיע על עדכון העלונים לרופא ולצרכן של התכשיר - Infanrix IPV- HIB / אינפנריקס אי.פי.וי. איץ.אי.בי.

לתשומת ליבכם העדכונים כוללים:

עדכון טכני במזרק ה Pre filled syringe של החיסון אינפנריקס אי.פי.וי. איץ.אי.בי ובעקבותיו עודכן הסעיף Instructions for the pre-filled syringe
שימו לב - לגבי ה Instructions for the pre-filled – יש להתייחס להוראות בעלון שנמצא באריזה (בשלב הראשון יהיו קיימים בשוק שני סוגי המזרקים)

בנוסף לכך, עדכון שם החיסון בעלון לצרכן בעברית בהתאם לרישיון התכשיר מ- אינפנריקס IPV- HIB ל- אינפנריקס אי.פי.וי. איץ.אי.בי.

וזאת בנוסף לעדכונים אחרים שנעשו בעלון ומפורטים מטה.

חומרים פעילים:

DIPHTHERIA TOXOID	NLT 30 IU / 0.5 ML
INACTIVATED POLIO VIRUS (IPV) TYPE 3	32 DU / 0.5 ML
INACTIVATED POLIO VIRUS (IPV) TYPE 2	8 DU / 0.5 ML
INACTIVATED POLIO VIRUS (IPV) TYPE 1	40 DU / 0.5 ML
PERTUSSIS TOXOID	25 MCG / 0.5 ML
FILAMENTOUS HAEMAGGLUTININ (FHA)	25 MCG / 0.5 ML
PERTACTIN	8 MCG / 0.5 ML
TETANUS TOXOID	NLT 40 IU / 0.5 ML
HAEMOPHILUS INFLUENZAE TYPE B POLYSACCHARIDE	10 MCG / 0.5 ML

ההתוויה העדכנית המאושרת לתכשיר בישראל:

Active immunisation in infants from the age of 2 months to 5 years against diptheria, tetanus, pertussis, poliomyelitis and Haemophilus influenza type b. Booster dose for children who have previously been immunised with DTP, Polio and Hib antigens.

בהודעה זו כלולים השינויים המהותיים בלבד. בעלונים ישנם שינויים נוספים.מקרא לעדכונים המסומנים:

- מידע שהוסר – מסומן בקו אדום חוצה **XXX**
- תוספת – כתב **כחול**
- תוספת החמרה - כתב **כחול** – מסומן בצהוב מרקר
- שינוי מיקום טקסט- **כתב ירוק**

6.5 Nature and contents of container

Powder in a vial (type I glass) containing 1 dose with a stopper (butyl rubber) and 0.5 ml of suspension in a pre-filled syringe (type I glass) with a plunger stopper (butyl rubber) and with a rubber tip cap.

The tip cap and rubber plunger stopper of the pre-filled syringe and the stopper of the vial are made with synthetic rubber.

~~with or without needles.~~ Pack sizes of 1 and 10 doses, with or without needles.

6.6 Special precautions for disposal and other handling

Upon storage of the DTPa-IPV suspension, a white deposit and clear supernatant can be observed in the syringe. This is not a sign of deterioration.

The pre-filled syringe should be well shaken to obtain a homogeneous suspension. The DTPa-IPV suspension in the pre-filled syringe, the Hib powder in the vial and the reconstituted vaccine should be inspected visually for any foreign particulate matter and/or abnormal physical appearance prior to administration. In the event of either is observed, the vaccine should be discarded.

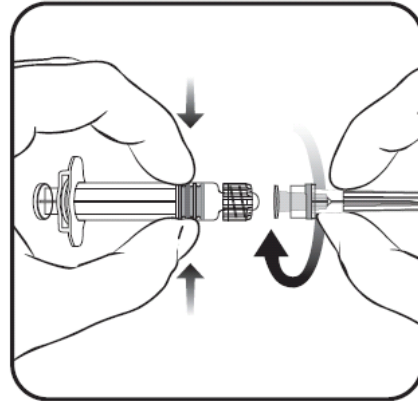
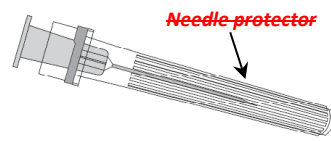
The vaccine is reconstituted by adding the entire contents of the pre-filled syringe of DTPa-IPV suspension to the vial containing the Hib powder. The mixture should then be injected immediately. The full reconstitution instructions are:

1. Shake the pre-filled syringe containing the DTPa-IPV suspension
2. Attach a needle to the pre-filled syringe of DTPa-IPV and inject the contents of the syringe into the Hib vial.
3. With the needle still inserted, shake the Hib vial vigorously and examine for complete dissolution.
4. Withdraw the entire mixture back into the syringe.
5. Replace the needle with an appropriate size needle for injection and administer the vaccine.
6. If the vaccine is not administered immediately, shake the solution vigorously again before injection.

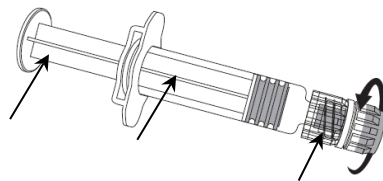
~~The pre-filled syringe can be supplied with either a ceramic coated treatment (CCT) of the luer tip or with a plastic rigid tip cap (PRTC) luer lock adaptor.~~

~~Instructions for use of pre-filled syringe if supplied with a PRTC luer lock adaptor~~

Needle

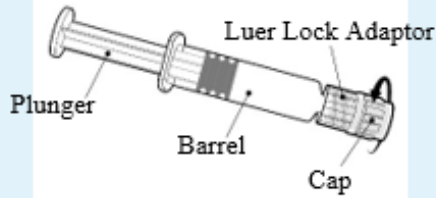


Syringe

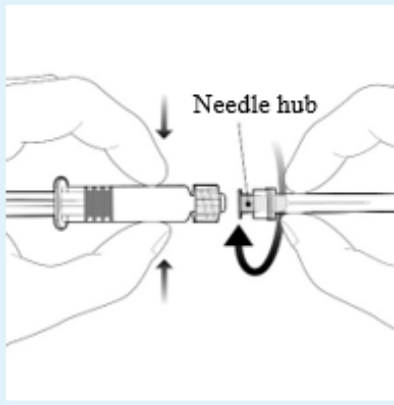


- 1.— Holding the syringe **barrel** in one hand (avoid holding the syringe plunger), unscrew the syringe cap by twisting it anticlockwise.
- 2.— To attach the needle to the syringe, twist the needle clockwise into the syringe until you feel it lock (see picture).
- 3.— Remove the needle protector, which on occasion can be a little stiff.
- 4.— Reconstitute the vaccine as described above.

Instructions for the pre-filled syringe



Hold the syringe by the barrel, not by the plunger.
Unscrew the syringe cap by twisting it anticlockwise.



To attach the needle, connect the hub to the Luer Lock Adaptor and rotate a quarter turn clockwise until you feel it lock.

Reconstitute the vaccine as described above.

Do not pull the syringe plunger out of the barrel. If it happens, do not administer the vaccine.

Disposal:

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

- **עדכונים מהותיים נעשו בסעיפים הבאים בעלון לצרכן:**

6. מידע נוסף

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כיצד נראית התרופה ומה תוכן האריזה:

מרכיב האינפנריקס אי.פי.וי. (IPV-) של החיסון אינפנריקס אי.פי.וי. איץ.אי.בי. **IPV-Hib** הוא תרחיף לבן, מעט חלבי, המגיע במזרק המוכן לשימוש (0.5 מ"ל).

מרכיב ה- איץ.אי.בי. (Hib-) של החיסון הוא אבקה המגיעה בבקבוקון נפרד. שני המרכיבים מעורבבים יחד ממש לפני שילדך מקבל את הזריקה.

גודלי אריזה: 1 ו- 10 מנות של בקבוקונים + מזרקים מוכנים לשימוש. ייתכן כי מחטים יצורפו לאריזה. ייתכן שלא כל גדלי האריזות משווקים.

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The following information is intended for healthcare professionals only:

Infanrix-IPV+Hib should not be mixed with other vaccines or medicinal products in the same syringe.

Upon storage of the DTPa-IPV suspension, a white deposit and clear supernatant can be observed in the syringe. This is not a sign of deterioration.

The pre-filled syringe should be well shaken to obtain a homogeneous suspension. The DTPa-IPV suspension in the pre-filled syringe, the Hib powder in the vial and the reconstituted vaccine should be inspected visually for any foreign particulate matter and/or abnormal physical appearance prior to administration. In the event of either is observed, the vaccine should be discarded.

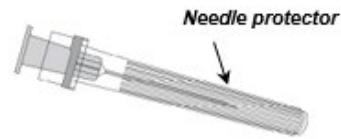
The vaccine is reconstituted by adding the entire contents of the pre-filled syringe of DTPa-IPV suspension to the vial containing the Hib powder. The mixture should then be injected immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and should normally not be longer than 8 hours at 2° C to 8° C (in a refrigerator). The full reconstitution instructions are:

1. Shake the pre-filled syringe containing the DTPa-IPV suspension
2. Attach a needle to the pre-filled syringe of DTPa-IPV and inject the contents of the syringe into the Hib vial.
3. With the needle still inserted, shake the Hib vial vigorously and examine for complete dissolution.
4. Withdraw the entire mixture back into the syringe.
5. Replace the needle with an appropriate size needle for injection and administer the vaccine.
6. If the vaccine is not administered immediately, shake the solution vigorously again before injection.

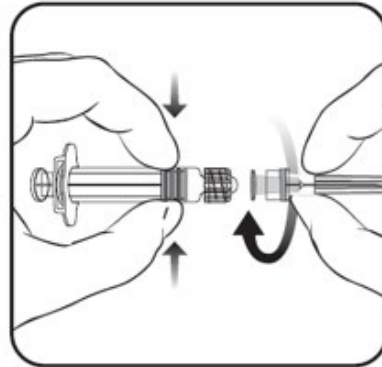
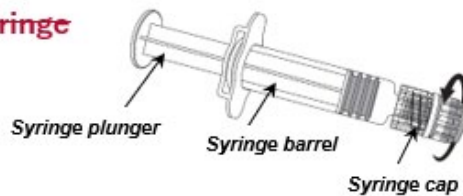
The pre-filled syringe can be supplied with either a ceramic coated treatment (CCT) of the luer tip or with a plastic rigid tip cap (PRTC) luer lock adaptor:

• Instructions for use of pre-filled syringe if supplied with a PRTC luer lock adaptor

Needle

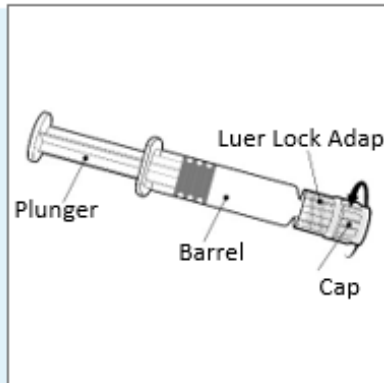


Syringe



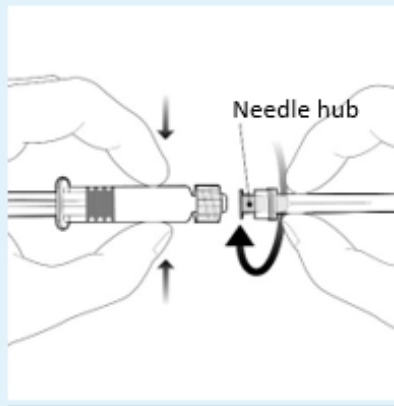
1. Holding the syringe **barrel** in one hand (avoid holding the syringe plunger), unscrew the syringe cap by twisting it anticlockwise.
2. To attach the needle to the syringe, twist the needle clockwise into the syringe until you feel it lock (see picture):
3. Remove the needle protector, which on occasion can be a little stiff.
4. Reconstitute the vaccine as described above:

Instructions for the pre-filled syringe



Hold the syringe by the barrel, not by the plunger.

Unscrew the syringe cap by twisting it anticlockwise.



To attach the needle, connect the hub to the Luer Lock Adaptor and rotate a quarter turn clockwise until you feel it lock.

Reconstitute the vaccine as described above.

Do not pull the syringe plunger out of the barrel. If it happens, do not administer the vaccine.

Disposal:

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.

העלון לרופא והעלון לצרכן נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות:

[מאגר התרופות\(health.gov.il\)](http://health.gov.il) וניתן לקבלם מודפסים על-ידי פניה לחברת גלקסומיתקליין רח' בזל 25 פתח תקוה בטלפון: 03-9297100.

בברכה,

מירי עזר שניידר

רוקחת ממונה