



יוני 2024

רופא/ה נכבד/ה, רוקח/ת נכבד/ה,

הנדון:

Leqvio 284mg, Solution for injection

לקוויו 284מ"ג, תמיסה להזרקה

התכשיר שבנדון רשום בישראל להתוויות הבאות:

Leqvio is indicated in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:

- in combination with a statin or statin with other lipid-lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin, or
- alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.

המרכיב הפעיל: Inclisiran (As Sodium) 189mg/ml

ברצוננו להודיעכם על עדכונים בעלון לצרכן של התכשיר שבנדון.

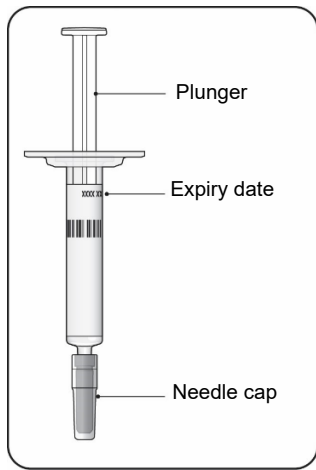
העדכונים מפורטים להלן (קו תחתי משמעו תוספת טקסט, **החמרות** מודגשות בצהוב):

עדכונים בעלון לצרכן מזרק מוכן לשימוש: (הוספת הנחיות הזרקה לצוות הרפואי)

המידע הבא מיועד לאנשי הצוות הרפואי בלבד:

הוראות שימוש בלקוויו מזרק מוכן לשימוש ללא מגן מחט:

This section contains information on how to inject Leqvio.



Important information you need to know before injecting Leqvio

- **Do not** use the pre-filled syringe if any of the seals on the outer carton or the seal of the plastic tray are broken.
- **Do not** remove the needle cap until you are ready to inject.
- **Do not** use if the pre-filled syringe has been dropped after removing the needle cap.
- **Do not** try to re-use or take apart the pre-filled syringe.

Step 1. Inspect the pre-filled syringe

You may see air bubbles in the liquid, which is normal. Do not try to remove the air.

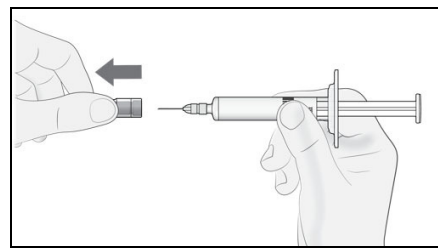
- **Do not** use the pre-filled syringe if it looks damaged or if any of the solution for injection has leaked out of the pre-filled syringe.

Step 2. Remove needle cap

Firmly pull straight to remove the needle cap from the pre-filled syringe. You may see a drop of liquid at the end of the needle. This is normal.

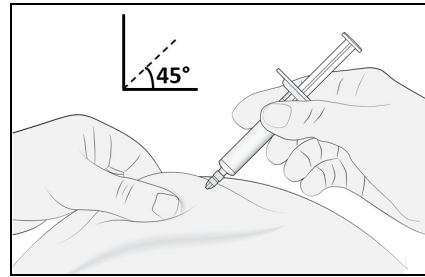
Do not put the needle cap back on. Throw it away.

Note: Do not remove the needle cap until you are ready to inject. Early removal of the needle cap prior to injection can lead to drying of the drug product within the needle, which can result in needle clogging.



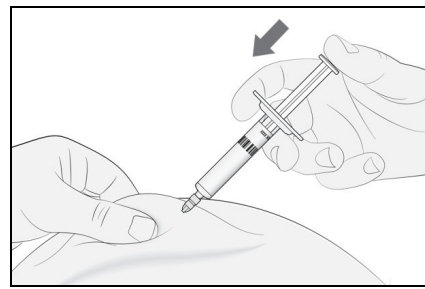
Step 3. Insert needle

Gently pinch the skin at the injection site and hold the pinch throughout the injection. With the other hand insert the needle into the skin at an angle of approximately 45 degrees as shown.

**Step 4. Inject**

Continue to pinch the skin. Slowly press the plunger as far as it will go. This will make sure that a full dose is injected.

Note: If you cannot depress the plunger following insertion of the needle, use a new pre-filled syringe.

**Step 5. Complete injection and dispose of the pre-filled syringe.**

Remove the pre-filled syringe from the injection site. Do not put the needle cap back on. Dispose of the pre-filled syringe in accordance with local requirements.

עדכונים בעלון לצרכן מזרק מוכן לשימוש עם מגן מחט: (עדכון הנחיות הזרקה לצוות הרפואי)

הוראות שימוש בלקוויו מזרק מוכן לשימוש עם מגן מחט:

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Step 2. Remove needle cap

Firmly pull straight to remove the needle cap from the pre-filled syringe. You may see a drop of liquid at the end of the needle. This is normal.

Do not put the needle cap back on. Throw it away.

Note: Do not remove the needle cap until you are ready to inject. Early removal of the needle cap prior to injection can lead to drying of the drug product within the needle, which can result in needle clogging.

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Step 4. Start injection

Continue to pinch the skin. Slowly press the plunger as far as it will go. This will make sure that a full dose is injected.

Note: If you cannot depress the plunger following insertion of the needle, use a new pre-filled syringe.

מומלץ לקרוא בעיון את כל תוכן העלונים.

העלונים נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלם מודפסים על-ידי פניה לבעל הרישום.

בברכה,
סיון דוד
רוקחת ממונה
נוברטיס ישראל בע"מ