

Tepkinly 4 mg / 0.8 ml
Tepkinly 48 mg
תמיסה להזרקה
solution for injection

חברת AbbVie Biopharmaceuticals Ltd. מבקשת להודיע על צורת מהילה חדשה עבור טפקינלי 4 מ"ג/0.8 מ"ל – צורת syringe to syringe. בעקבות כך העלון לרופא ולצרכן של התכשירים שבנדון עודכנו. בנוסף, העלון לצרכן של התכשירים עודכן בהנחיות הנוגעות להידרציה בזמן הטיפול. בהודעה זו מצוינים החמרות וסעיפים שבהם נעשה שינוי מהותי. מידע שהתווסף מסומן **באדום**, והחמרות מסומנות **בצהוב**.

ההתוויות המאושרות לתכשיר:

Tepkinly is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from indolent lymphoma, and high-grade B cell lymphoma after two or more lines of systemic therapy.

Tepkinly as monotherapy is indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.

להלן השינויים בעלון לצרכן:

3. כיצד תשתמש בתרופה?

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במהלך החודש הראשון (מחזור 1) שבו ניתן לך טפקינלי:

- **חשוב שתהיה רווי היטב בנוזלים. מסיבה זו הרופא שלך עשוי להורות לך לשתות הרבה מים ביום שלפני וביום שאחרי קבלת טפקינלי. ביום שבו אתה מקבל טפקינלי, הרופא שלך עשוי לתת לך עירווי נוזלים באמצעות מחט דרך הוריד (מתן תוך-וריד).**
- **אם אתה נוטל תרופה לטיפול בלחץ דם גבוה, הרופא שלך עשוי לבקש ממך להפסיק ליטול אותה לפרק זמן קצר בזמן שאתה מטופל בטפקינלי.**

6.6 Special precautions for disposal and other handling

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Tepkinly 4 mg/0.8 ml

Preparation of epcoritamab

This entire section must be read carefully before preparation of epcoritamab. **Certain doses** (the priming (0.16 mg) and intermediate dose (0.8 mg)) of epcoritamab require **dilution** prior to administration. Epcoritamab can be diluted using two different methods which are either the vial method or the syringe method. All instructions provided below must be followed as improper preparation may lead to improper dose.

Epcoritamab has to be prepared using aseptic technique. Filtration of the diluted solution is not required.

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Preparation of diluted epcoritamab using the sterile syringe method

0.16 mg priming dose preparation instructions - 2 dilutions required – sterile syringe method

Use an appropriately sized syringe and needle for each transfer step.

<p>1) <u>Prepare epcoritamab vial</u></p> <ul style="list-style-type: none"> a. <u>Retrieve one 4 mg/0.8 ml epcoritamab vial with the light blue cap from the refrigerator.</u> b. <u>Allow the vial to come to room temperature for no more than 1 hour.</u> c. <u>Gently swirl the epcoritamab vial.</u> <p><u>DO NOT</u> vortex or vigorously shake the vial.</p>
<p>2) <u>Perform first dilution</u></p> <ul style="list-style-type: none"> a. <u>Label an appropriately sized syringe as “dilution A”.</u> b. <u>Withdraw 4.2 ml of sodium chloride 9 mg/ml (0.9%) sterile solution into the dilution A syringe. Include approximately 0.2 ml air in the syringe.</u> c. <u>In a new syringe labelled as “syringe 1”, withdraw 0.8 ml of epcoritamab.</u> d. <u>Connect the two syringes and push the 0.8 ml of epcoritamab into the dilution A syringe. The initially diluted solution contains 0.8 mg/ml of epcoritamab.</u> e. <u>Gently mix by inverting the connected syringes 180 degrees 5 times.</u> f. <u>Disconnect the syringes and discard syringe 1.</u>
<p>3) <u>Perform second dilution</u></p> <ul style="list-style-type: none"> a. <u>Label an appropriately sized syringe as “dilution B”.</u> b. <u>Withdraw 8 ml of sodium chloride 9 mg/ml (0.9%) sterile solution into the dilution B syringe. Include approximately 0.2 ml air in the syringe.</u> c. <u>Label another appropriately sized syringe as “syringe 2”.</u> d. <u>Connect syringe 2 to the dilution A syringe and transfer 2 ml of solution into syringe 2. The dilution A syringe is no longer needed and should be discarded.</u> e. <u>Connect syringe 2 to the dilution B syringe and push the 2 ml of solution into the dilution B syringe to make a final concentration of 0.16 mg/ml.</u>

<p>f. <u>Gently mix by inverting the connected syringes 180 degrees 5 times.</u></p> <p>g. <u>Disconnect the syringes and discard syringe 2.</u></p>
<p>4) <u>Withdraw dose</u></p> <p><u>Connect and transfer 1 ml of the diluted epcoritamab from the dilution B syringe into a new syringe. The dilution B syringe is no longer needed and should be discarded.</u></p>
<p>5) <u>Label syringe</u></p> <p><u>Label the syringe with the product name, dose strength (0.16 mg), date and the time of day.</u></p>
<p>6) <u>Discard the vial and any unused portion of epcoritamab in accordance with local requirements.</u></p>

0.8 mg intermediate dose preparation instructions - 1 dilution required – sterile syringe method

Use an appropriately sized syringe and needle for each transfer step.

<p>1) <u>Prepare epcoritamab vial</u></p> <p>a. <u>Retrieve one 4 mg/0.8 ml epcoritamab vial with the light blue cap from the refrigerator.</u></p> <p>b. <u>Allow the vial to come to room temperature for no more than 1 hour.</u></p> <p>c. <u>Gently swirl the epcoritamab vial.</u></p> <p>DO NOT vortex or vigorously shake the vial.</p>
<p>2) <u>Perform dilution</u></p> <p>a. <u>Label an appropriately sized syringe as “dilution A”.</u></p> <p>b. <u>Withdraw 4.2 ml of sodium chloride 9 mg/ml (0.9%) sterile solution into the dilution A syringe. Include approximately 0.2 ml air in the syringe.</u></p> <p>c. <u>In a new syringe labelled as “syringe 1”, withdraw 0.8 ml of epcoritamab.</u></p> <p>d. <u>Connect the two syringes and push the 0.8 ml of epcoritamab into the dilution A syringe to make a final concentration of 0.8 mg/ml.</u></p> <p>e. <u>Gently mix by inverting the connected syringes 180 degrees 5 times.</u></p> <p>f. <u>Disconnect the syringes and discard syringe 1.</u></p>
<p>3) <u>Withdraw dose</u></p> <p><u>Connect a new syringe to the dilution A syringe and transfer 1 ml of the diluted epcoritamab into the new syringe. The dilution A syringe is no longer needed and should be discarded.</u></p>
<p>4) <u>Label syringe</u></p> <p><u>Label the syringe with the product name, dose strength (0.8 mg), date and the time of day.</u></p>
<p>5) <u>Discard the vial and any unused portion of epcoritamab in accordance with local requirements.</u></p>

העלונים המעודכנים לרופא ולצרכן נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלם מודפסים על ידי פניה לבעל הרישום, AbbVie Biopharmaceuticals Ltd, רחוב החרש 4, הוד השרון או בטלפון 7909600 – 09.

בברכה,
חברת אבווי ביופארמה בע"מ