פייזר פרמצבטיקה ישראל בע"מ
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הרצליה פיתוח, ישראל 46725
טל: 972-9-9700500 פקס: 972-9-9700501

דצמבר 2021

רופא/ה, רוקח/ת נכבד/ה,

ברצוננו להודיעך על עדכון בעלון לרופא של: **MYLOTARG**

(POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION)

מיילוטארג

<u>המרכיב הפעיל:</u>

GEMTUZUMAB OZOGAMICIN 5 MG/VIAL

<u>Indicated for:</u>
MYLOTARG is indicated for the treatment of newly-diagnosed CD33-positive acute myeloid leukemia in adults.
MYLOTARG is indicated for the treatment of relapsed or refractory CD33-positive acute myeloid leukemia in adults and in pediatric patients 2 years and older.

<u>להלן העדכונים העיקריים בעלון לרופא:</u>

5. DOSAGE AND ADMINISTRATION

5.4 Instructions for Reconstitution, Dilution, and Administration

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<u>Reconstitution</u>

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- MYLOTARG is a cytotoxic drug. Follow applicable special handling and disposal procedures.
- Calculate the dose (mg) and number of vials of MYLOTARG required.
- Prior to reconstitution, allow drug product vials to reach room temperature (up to 30°C) for approximately 5 minutes.
- Reconstitute each vial with 5 mL of Sterile Water for Injection, to obtain a concentration of 1 mg/mL of MYLOTARG that delivers at least 4.5 mL (4.5 mg).
- Gently swirl the vial to aid dissolution. DO NOT SHAKE.
- Inspect the reconstituted solution for particulates and discoloration. The reconstituted solution may contain small white to off-white, opaque to translucent, and amorphous to fiber-like particles.
- MYLOTARG contains no bacteriostatic preservatives.
- If the reconstituted solution cannot be used immediately, it may be stored in the original vial for up to 16 hours in a refrigerator (2°C to 8°C) or up to 3 hours at room temperature (up to 30°C).. **PROTECT FROM LIGHT. DO NOT FREEZE**.

* The minimum amount that can be extracted is 4.5 mg/vial.

<u>Dilution</u>

- Calculate the required volume of the reconstituted solution needed to obtain the appropriate dose according to patient body surface area. Withdraw this amount from the vial(s) using a

syringe. PROTECT FROM LIGHT. Discard any unused reconstituted solution left in the vial.

Doses must be mixed to a concentration between 0.075 mg/mL to 0.234 mg/mL according to the following instructions:

- Doses less than 3.9 mg must be prepared for administration by syringe. Add the reconstituted MYLOTARG solution to a syringe with 0.9% Sodium Chloride Injection to a final concentration between 0.075 mg/mL to 0.234 mg/mL. PROTECT FROM LIGHT.
- Doses greater than or equal to 3.9 mg are to be diluted in a syringe or a polyvinyl chloride (PVC) with di(2-ethylhexyl)phthalate (DEHP), non-PVC polyolefin, or ethylene vinyl acetate intravenous infusion bag in an appropriate volume of 0.9% Sodium Chloride Injection to ensure a final concentration between 0.075 mg/mL to 0.234 mg/mL. PROTECT FROM LIGHT.
- Gently invert the infusion container to mix the diluted solution. DO NOT SHAKE.
- Following dilution with 0.9% Sodium Chloride Injection, MYLOTARG solution should be infused immediately. If not used immediately, the diluted solution may be stored up to 18 hours in a refrigerator (2°C to 8°C) and for up to 6 hours at room temperature (up to 30°C). The allowed time at room temperature (up to 30°C) includes the time required for preparation of the diluted solution, equilibration, if needed, and the 2 hours needed to administer to the patient. PROTECT FROM LIGHT and DO NOT FREEZE.

Administration

- **Use an in-line 0.2 micron polyethersulfone (PES) filter for infusion of MYLOTARG.**
- Protect the intravenous bag from light using a light-blocking cover during infusion. The infusion line does not need to be protected from light.
- Infuse the diluted solution over 2 hours using an infusion set made of polyvinyl chloride (PVC) with DEHP, PVC non-DEHP, polyethylene, or polyurethane. The infusion must be completed prior to the end of the allowed 6-hour storage of the diluted solution at room temperature (up to 30°C).
- Do not mix MYLOTARG with, or administer as an infusion with, other medicinal products.

8 WARNINGS AND PRECAUTIONS

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8.7 Excipients

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Excipients

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

This medicinal product may be further prepared for administration with sodium-containing solutions and this should be considered in relation to the total sodium from all sources that will be administered to the patient.

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15.1 Storage and Handling

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Refrigerate (2-8°C) MYLOTARG vials and store in the original carton to protect from light. DO NOT FREEZE.

MYLOTARG is a cytotoxic drug. Follow applicable special handling and disposal procedures.

- Use reconstituted solution immediately. If the reconstituted solution cannot be used immediately, it may be stored in the original vial for up to 16 hours in a refrigerator (2°C to 8°C) or up to 3 hours at room temperature (up to 30°C). **PROTECT FROM LIGHT. DO NOT FREEZE.**

- MYLOTARG diluted solution should be infused immediately. If not used immediately, the diluted solution may be stored up to 18 hours in a refrigerator (2°C to 8°C) and for up to 6 hours at room temperature (up to 30°C). The allowed time at room temperature (up to 30°C) includes the time required for preparation of the diluted solution, equilibration, if needed, and the 2 hours needed to administer to the patient.. PROTECT FROM LIGHT and DO NOT FREEZE.
- The reconstituted solutions should be diluted with 0.9% sodium chloride injection.

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כמו כן, בוצעו שינויים נוספים הכוללים תוספת מידע, השמטת מידע ועדכוני נוסח שאינם מהווים החמרה. העלונים המעודכנים זמינים באתר משרד הבריאות.

https://data.health.gov.il/drugs/index.html#!/byDrug

לחילופין, לקבלת עלון מלא מודפס ניתן לפנות לחברת פייזר פרמצבטיקה ישראל בע"מ, שנקר 9, ת.ד. 12133
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בברכה,
עידית שלם אבידר
רוקחת ממונה