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יולי 2020

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>

10. USE IN SPECIFIC POPULATIONS

10.1 Pregnancy
<u>Risk Summary</u>
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There are no available data on MYLOTARG use in pregnant women to evaluate for a drug-associated risk. In animal reproduction studies, gemtuzumab ozogamicin caused embryo-fetal toxicity, including structural abnormalities and alterations to growth, at maternal systemic exposures that were greater than or equal to 0.4 times the exposure in patients at the maximum recommended dose, based on AUC *(see Data)*. Advise pregnant women of the potential risk to a fetus.
The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes.
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10.2 Lactation
<u>Risk Summary</u>
There are no data on the presence of gemtuzumab ozogamicin or its metabolites in human milk, the effects on the breastfed infant, or the effects on milk production. Because of the potential for serious adverse reactions in the breastfed infant, advise, women not to breastfeed during treatment with MYLOTARG and for at least 1- month after the final dose.
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10.4 Pediatric Use
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The safety and effectiveness of MYLOTARG as a single agent in pediatric patients with newly-diagnosed AML have not been established.
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The safety and effectiveness of MYLOTARG as a single agent in pediatric patients less than 2 years of age with relapsed or refractory AML have not been established

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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 הרצליה פיתוח, 46725.

בברכה,
עידית שלם אבידר
רוקחת ממונה

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