פייזר פרמצבטיקה ישראל בע"מ
רח' שנקר 9, ת.ד. 12133
הרצליה פיתוח, ישראל 46725
טל: 972-9-9700500 פקס: 972-9-9700501

אפריל 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>

12.3 Pharmacokinetics

There are no clinical PK data for the fractionated regimen. When gemtuzumab ozogamicin is administered at 9 mg/m^2 (2 doses, 14 days apart), the C_{max} following the first dose for patients who received 9 mg/m^2 gemtuzumab ozogamicin was 3.0 mg/L and increased to 3.6 mg/L after the second dose.

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14. CLINICAL STUDIES

14.1 Newly-Diagnosed CD33-positive AML

<u>Study ALFA-0701</u>
MYLOTARG in combination with chemotherapy was investigated in ALFA-0701 (NCT00927498), a multicenter, randomized, open-label Phase 3 study of 271 patients with newly-diagnosed de novo AML age 50 to 70 years. Patients were randomized (1:1) to receive induction therapy consisting of daunorubicin (60 mg/m^2 on Days 1 to 3) and cytarabine (200 mg/m^2 on Days 1 to 7) (DA) with (n=135) or without (n=136) MYLOTARG 3 mg/m^2 (up to maximum of one vial) on Days 1, 4 and 7. Patients who did not achieve a response after first induction could receive a second induction with daunorubicin and cytarabine alone (<u>daunorubicin 35 mg/m^2/day on Days 1 and 2, and cytarabine 1 g/m^2 every 12 hours, on Day 1 to Day 3 without MYLOTARG</u>). Patients with response received consolidation therapy with 2 courses of treatment including daunorubicin (60 mg/m2 on Day 1 of consolidation course 1; 60 mg/m2 on Days 1 and 2 of consolidation course 2) and cytarabine (1 g/m2 every 12 hours on Days 1 to 4) with or without MYLOTARG 3 mg/m2 (up to a maximum of one vial) on Day 1 according to their initial randomization. Patients who experienced remission were also eligible for allogeneic transplantation. An interval of at least 2 months between the last dose of MYLOTARG and transplantation was recommended.

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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 PFE פרמצבטיקה ישראל בע"מ, שנקר 9, ת.ד. 12133 הרצליה פיתוח, 46725.

בברכה,
עידית שלם אבידר
רוקחת ממונה