



Bayer HealthCare Bayer Schering Pharma

רוקח/ת נכבד/ה,

הרינו להודיעך על עדכון העלון לרופא ו/או העלון לצרכן של התכשירים המפורטים בהמשך. בפירוט שלהלן כלולים השינויים העיקריים בלבד. תוספות המידע מסומנות בקו תחתון, מחיקות מידע בקו אמצעי. העלונים לרופא ולצרכן מפורסמים במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלם מודפס ע"י פניה לחברת באייר ישראל, רח' החרש 36 הוד השרון, טלפון: 09-7626700.

Zevalin זבלין

צורת מינון: ערכה לעירו

הרכב וחוזק: Ibritumomab tiuxetan 1.6 mg/ml

אושרה תוספת התוויה לתכשיר.

ההתוויה המאושרת:

The [90Y]-radiolabelled Zevalin is indicated for the treatment of adult patients with rituximab relapsed or refractory CD20 + follicular B-cell non-Hodgkin's lymphoma (NHL).

The [90Y]-radiolabelled Zevalin is indicated as consolidation therapy after remission induction in previously untreated patients with follicular lymphoma. The benefit of Zevalin following rituximab in combination with chemotherapy has not been established.

סעיפים נוספים שעודכנו ופירוט השינויים בעלון לרופא:

• **Posology and method of administration**

The recommend radioactivity for patients receiving Zevalin as consolidation after remission induction is:

- patients with 150,000 platelets per mm³ and more: 15 MBq [90Y]-radiolabelled Zevalin per kg body weight up to a maximum of 1200 MBq.

- patients with fewer than 150,000 platelets per mm³ should not receive Zevalin consolidation treatment.

Children – There is no experience in children and adolescents below 18 years of age.

• **Special Warnings and Special Precautions for Use**

Patients receiving Zevalin as consolidation should have recovered from induction chemotherapy and have achieved a neutrophil count > 1,500/mm³ and a platelet count > 150,000/mm³ before Zevalin administration.

Zevalin should not be administered in patients receiving Zevalin as consolidation after remission induction with platelet counts <150,000/mm³

Patients should not receive growth factor treatment such as G-CSF for 2 weeks prior to Zevalin treatment as well as for 2 weeks following completion of the regimen because of the potential sensitivity of rapidly dividing myeloid cells to radiation.

No data available on patients with CNS-lymphoma as those patients were not included in clinical studies.

- **Undesirable Effects**

Following Zevalin as consolidation after first line remission induction, the median times to recovery were 20 days and 35 days for Grade 3 or 4 thrombocytopenia and 20 days and 28 days for Grade 3 or 4 neutropenia.

In the study with 204 patients receiving Zevalin as consolidation following first-line remission induction, infections were observed more frequently than as described in the above table (very common).

In addition, the following adverse drug reactions were observed in this study:

- MedDRA SOC General disorders and administration site conditions: fatigue (very common)

- MedDRA SOC Vascular disorders: petechia (very common), hypertension (common), hypotension (common)

- MedDRA SOC Reproductive system and breast disorders: amenorrhoea (common).

בברכה,
אילה שניידר הנדלסמן
רוקחת ממונה