



## **MabThera (rituximab) 10mg/ml IV**

### **Concentrate for solution for intravenous infusion**

רופא/ה יקר/ה, רוקח/ת יקר/ה,

חברת רוש פרמצבטיקה (ישראל) בע"מ מבקשת להודיעכם על עדכון בעלון לרופא של התכשיר מבטרה 10מ"ג/מ"ל IV. בהודעה זו מצוינים רק עדכונים מהותיים ועדכונים אשר מהווים החמרה.

#### **ההתוויות הרשומות לתכשיר בישראל:**

##### Non-Hodgkin's lymphoma (NHL)

MabThera is indicated for the treatment of patients with relapsed or refractory low-grade or follicular, B-cell non-hodgkin's lymphoma.

MabThera is indicated for the treatment of previously untreated patients with low-grade or follicular lymphoma in combination with chemotherapy

MabThera is indicated for the treatment of patients with CD20 positive diffuse large B-cell non-Hodgkin's lymphoma in combination with CHOP chemotherapy.

MabThera maintenance therapy is indicated for the treatment of follicular lymphoma patients responding to induction therapy.

##### Chronic lymphocytic leukaemia (CLL)

MabThera in combination with chemotherapy is indicated for the treatment of patients with previously untreated and relapsed/refractory chronic lymphocytic leukaemia. Only limited data are available on efficacy and safety for patients previously treated with monoclonal antibodies including MabThera or patients refractory to previous MabThera plus chemotherapy.

##### Rheumatoid arthritis

MabThera is indicated, in combination with methotrexate, to reduce signs and symptoms in adult patients with moderately to severely active rheumatoid arthritis who had an inadequate response or intolerance to one or more TNF antagonist therapies.

##### Granulomatosis with polyangiitis and Microscopic polyangiitis

MabThera, in combination with glucocorticoids, is indicated for the treatment of adult patients with Granulomatosis with polyangiitis (GPA) (Wegener's Granulomatosis (WG)) and Microscopic polyangiitis (MPA).

##### Pemphigus vulgaris

MabThera is indicated for the treatment of adult patients with moderate to severe pemphigus vulgaris (PV).

#### **הסבר:**

טקסט עם קו תחתו מצוין טקסט שהוסף לעלון.  
טקסט עם קו חוצה מצוין טקסט שהוסר מן העלון.

למידע נוסף יש לעיין בעלון לרופא כפי שאושר ע"י משרד הבריאות.

העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על-ידי פנייה לבעל הרישום: רוש פרמצבטיקה (ישראל) בע"מ, ת.ד. 6391, הוד השרון 4524079 טלפון 09-9737777. כתובתנו

באינטרנט: [www.roche.co.il](http://www.roche.co.il)

ב ב ר כ ה,

לילי אדר

רוקחת ממונה

Roche Pharmaceuticals (Israel) Ltd  
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## 6.6 Special precautions for disposal and other handling

[...]

Use a sterile needle and syringe to prepare MabThera. Aseptically withdraw the necessary amount of MabThera, and dilute to a calculated concentration of 1 to 4 mg/mL rituximab into an infusion bag containing sterile, pyrogen-free sodium chloride 9 mg/mL (0.9%) solution for injection or 5% D-Glucose in water. For mixing the solution, gently invert the bag in order to avoid foaming. Care must be taken to ensure the sterility of prepared solutions. Since the medicinal product does not contain any anti-microbial preservative or bacteriostatic agents, aseptic technique must be observed. Parenteral medicinal products should be inspected visually for particulate matter and discolouration prior to administration.

[...]