אוקטובר 2022

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 leukemia. 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 תחתי מציין טקסט שהוסף לעלון.
~~טקסט עם קו חוצה~~ מציין 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.

ב ב ר כ ה,

בתאור צפרי-חגג
מחלקת רישום

לילי אדר
רוקחת ממונה

Roche Pharmaceuticals (Israel) Ltd
Drugs regulatory affairs

6 Hacharash St.
P.O.B. 6391
Hod Hasharon 4524079

Tel. + 972-9-9737777
Fax + 972-9-9737850

4.4 Fertility, pregnancy and lactation

Breast-feeding

Limited data on rituximab excretion into breast milk suggest very low rituximab concentrations in milk ~~levels~~ (relative infant dose less than 0.4%). Few cases of follow-up of breastfed infants describe normal growth and development up to ~~1.5~~2 years. However, as these data are limited and the long-term outcomes of breastfed infants remain unknown, breast-feeding is not recommended while being treated with rituximab and optimally for ~~12~~ 6 months following rituximab treatment.

4.8 Undesirable effects

…

Table 2 Summary of adverse reactions reported in clinical trials or during postmarketing surveillance occurring in patients with rheumatoid arthritis receiving MabThera

MedDRA System Organ Class	Very Common	Common	Uncommon	Rare	Very rare	Not known
Infections and Infestations	upper respiratory tract infection, urinary tract infections	Bronchitis, sinusitis, gastroenteritis, tinea pedis			PML, reactivation of hepatitis B	serious viral infection[1]
…						

[1] See also section infections below.

Description of selected adverse reactions

…

Infections

The overall rate of infection reported from clinical trials was approximately 94 per 100 patient years in MabThera treated patients. The infections were predominately mild to moderate and consisted mostly of upper respiratory tract infections and urinary tract infections. The incidence of infections that were serious or required IV antibiotics was approximately 4 per 100 patient years. The rate of serious infections did not show any significant increase following multiple courses of MabThera. Lower respiratory tract infections (including pneumonia) have been reported during clinical trials, at a similar incidence in the MabThera arms compared to control arms.

In the post marketing setting, serious viral infections have been reported in RA patients treated with rituximab.

…

Table 3 Adverse Reactions occurring at 6-months in ≥ 5% of adult patients receiving MabThera in GPA/MPA Study (Rituximab n=99, and at a higher frequency than the comparator group), or during postmarketing surveillance.

MedDRA System organ class Adverse reaction	Frequency
Infections and infestations	
Urinary tract infection	7%
Bronchitis	5%
Herpes zoster	5%
Nasopharyngitis	5%
Serious viral infection[1]	not known
…	

[1] Observed during post-marketing surveillance. See also section infections below.

Description of selected adverse reactions

….

Infections

In the 99 MabThera patients, the overall rate of infection was approximately 237 per 100 patient years (95% CI 197 - 285) at the 6-month primary endpoint. Infections were predominately mild to moderate and consisted mostly of upper respiratory tract infections, herpes zoster and urinary tract infections. The rate of serious infections was approximately 25 per 100 patient years. The most frequently reported serious infection in the MabThera group was pneumonia at a frequency of 4%.

In the post marketing setting, serious viral infections have been reported in GPA/MPA patients treated with rituximab.

…

Table 4 Adverse reactions in MabThera-treated pemphigus vulgaris patients in PV Study 1 (up to month 24) and PV Study 2 (up to Week 52), or during postmarketing surveillance

MedDRA System Organ Class	Very Common	Common	Not known
Infections and infestations	Upper respiratory tract infection	Herpes virus infection Herpes zoster Oral herpes Conjunctivitis Nasopharyngitis Oral candidiasis Urinary tract infection	serious viral infection[1]
…			

[1] See also section infections below.

Infections

In the post marketing setting, serious viral infections have been reported in PV patients treated with rituximab.