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אוקטובר 2023

רופא/ה, רוקח/ת נכבד/ה,

ברצוננו להודיעך על עדכון בעלון לרופא של התכשיר

Ruxience

המרכיב הפעיל:

Rituximab

התוויה:

Ruxience is indicated for the following indications:
Non-Hodgkin's lymphoma (NHL)
Ruxience is indicated for the treatment of patients with relapsed or refractory low-grade or follicular, B-cell non-hodgkin's lymphoma.
Ruxience is indicated for the treatment of previously untreated patients with low-grade or follicular lymphoma in combination with chemotherapy.
Ruxience is indicated for the treatment of patients with CD20 positive diffuse large B- cell non-Hodgkin's lymphoma in combination with CHOP chemotherapy.
Ruxience maintenance therapy is indicated for the treatment of follicular lymphoma patients responding to induction therapy.

Chronic lymphocytic leukaemia (CLL)
Ruxience 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 Ruxience or patients refractory to previous Ruxience plus chemotherapy.

Rheumatoid arthritis
Ruxience 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
Ruxience, 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
Ruxience is indicated for the treatment of adult patients with moderate to severe pemphigus vulgaris (PV)

להלן העדכונים העיקריים בעלון לרופא:

4.4 Special warnings and precautions for use

Non Hodgkin's lymphoma and chronic lymphocytic leukaemia
Infections
……

Cases of enteroviral meningoencephalitis including fatalities have been reported following use of rituximab.

False negative serologic testing of infections
Due to the risk of false negative serologic testing of infections, alternative diagnostic tools should be considered in case of patients presenting with symptoms indicative of rare infectious disease e.g. West Nile virus and neuroborreliosis
…..

Rheumatoid arthritis, granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA), and pemphigus vulgaris

Infections

……

Cases of enteroviral meningoencephalitis including fatalities have been reported following use of rituximab.

False negative serologic testing of infections
Due to the risk of false negative serologic testing of infections, alternative diagnostic tools should be considered in case of patients presenting with symptoms indicative of rare infectious disease e.g. West Nile virus and neuroborreliosis

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4.8 Undesirable effects

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ADRs reported in clinical trials or during post-marketing surveillance in patients with NHL and CLL disease treated with rituximab monotherapy/maintenance or in combination with chemotherapy **Table 1**

MedDRA System Organ Class	Very Common	Common	Uncommon	Rare	Very Rare	Not Known
Infections and infestations	bacterial infections, viral infections, +bronchitis	sepsis, +pneumonia, +febrile infection, +herpes zoster, +respiratory tract infection, fungal infections, infections of unknown aetiology, +acute bronchitis, +sinusitis, hepatitis B[1]		serious viral infection[2], Pneumocystis jirovecii	PML	enteroviral meningoencephalitis[2, 3]

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Description of selected adverse reactions

Infections

….. The majority of patients had received rituximab in combination with chemotherapy or as part of a hematopoietic stem cell transplant. Examples of these serious viral infections are infections caused by the herpes viruses (Cytomegalovirus, Varicella Zoster Virus and Herpes Simplex Virus), JC virus (progressive multifocal leukoencephalopathy (PML)), enterovirus (meningoencephalitis) and hepatitis C virus (see section 4.4.).

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Table 2 Summary of adverse reactions reported in clinical trials or during post-marketing surveillance occurring in patients with rheumatoid arthritis receiving rituximab

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] enteroviral meningoencephalitis[2]

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Table 3 Adverse reactions occurring at 6-months in ≥ 5% of adult patients receiving rituximab 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	
….	...
Enteroviral meningoencephalitis	not known

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Table 4 Adverse reactions in rituximab-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[1,2] Enteroviral meningoencephalitis[1]

השינויים המודגשים ברקע צהוב מהווים החמרה. כמו כן, בוצעו שינויים נוספים בעלון לרופא ולצרכן הכוללים תוספת מידע, השמטת מידע ועדכוני נוסח שאינם מהווים החמרה. בהודעה זו מצוינים רק העדכונים העיקריים .קיימים עדכונים נוספים.
העלונים המעודכנים נשלחו למשרד הבריאות לצורך פרסומם במאגר התרופות שבאתר משרד הבריאות:
https://www.old.health.gov.il/units/pharmacy/trufot/index.asp?safa=h לחילופין, לקבלת עלונים מלאים מודפסים ניתן לפנות לחברת פייזר פרמצבטיקה ישראל בע"מ שנקר 9, ת.ד. 12133 הרצליה פיתוח, 46725.

בברכה,
אנה רזניקוב,
רוקחת ממונה