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נובמבר 2022

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:

4.8 Undesirable effects

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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]

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Description of selected adverse reactions

Infections

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

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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	~~Rituximab (n=99)~~Frequency
Infections and infestations	
Serious viral infection[1]	not known

Description of selected adverse reactions

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Infections

……

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

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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]

Description of selected adverse reactions

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Infections

……

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

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 בעלונים המעודכנים נשלחו למשרד הבריאות לצורך פרסום 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