ספטמבר 2026

RIXATHON®
rituximab

רופא/ה נכבד/ה,

רוקח/ת נכבד/ה,

חברת סנדוז פרמצבטיקה ישראל בע"מ מבקשת להודיעכם על עדכון העלון של התכשיר עודכן:

שם תכשיר	מספר רישום
Rixathon	162-10-35741-00

המרכיב הפעיל הינו: rituximab 10mg/ml

<u>ההתוויות הרשומות לתכשיר בישראל הינן:</u>

Rixathon is indicated for the following indications:

<u>* Non-Hodgkin’s lymphoma (NHL):</u>

Rixathon is indicated for the treatment of patients with relapsed or refractory low-grade or follicular, B-cell nonhodgkin’s lymphoma.

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

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

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

<u>* Chronic lymphocytic leukaemia (CLL):</u>

Rixathon 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 Rixathon or patients refractory to previous Rixathon plus chemotherapy.

<u>* Granulomatosis with polyangiitis and Microscopic polyangiitis:</u>

Rixathon, 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).

<u>*Pemphigus vulgaris (PV):</u>

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

<u>*Rheumatoid arthritis</u>

Rixathon 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.

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות:

https://data.health.gov.il/drugs/index.html#/byDrug

לעדכונכם בברכה,

מגר' דפנה סנדובסקי

רוקחת ממונה

סנדוז פרמצבטיקה ישראל בע"מ

<u>השינויים בעלון לרופא:</u>

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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Each 10 mL vial contains 7.0 mg of polysorbate 80 (E 433).
Each 50 mL vial contains 35.0 mg of polysorbate 80 (E 433).

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4. CLINICAL PARTICULARS

4.2 Posology and method of administration

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

In patients with rheumatoid arthritis or pemphigus vulgaris, premedication with 100 mg intravenous methylprednisolone should be completed 30 minutes prior to Rixathon infusions to decrease the incidence and severity of infusion related reactions (IRRs).

In patients with granulomatosis with polyangiitis (Wegener's) or microscopic polyangiitis, methylprednisolone given intravenously for 1 to 3 days at a dose of 1000 mg per day is recommended prior to the first infusion of Rixathon (the last dose of methylprednisolone may be given on the same day as the first infusion of Rixathon). This should be followed by oral prednisone 1 mg/kg/day (not to exceed 80 mg/day and tapered as rapidly as possible based on clinical need) during and after the 4-week induction course of Rixathon treatment.

Pneumocystis jirovecii pneumonia (PJP) prophylaxis is recommended for patients with GPA/MPA or PV during and following Rixathon treatment, as appropriate according to local clinical practice guidelines.

Posology
It is important to check the medicinal product labels to ensure that the appropriate formulation is being given to the patient, as prescribed.

Dose adjustments during treatment
No dose reductions of Rixathon are recommended. When Rixathon is given in combination with chemotherapy, standard dose reductions for the chemotherapeutic medicinal products should be applied.

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4.3 Contraindications

~~Contraindications for use in non-Hodgkin's lymphoma and chronic lymphocytic leukaemia~~

Hypersensitivity to the active substance or to murine proteins, or to any of the other excipients listed in section 6.1.

Active, severe infections (see section 4.4). Patients in a severely immunocompromised state.

~~Contraindications for use in rheumatoid arthritis,~~

~~granulomatosis with polyangiitis (GPA), microscopic~~

~~polyangiitis (MPA) and pemphigus vulgaris~~

~~Hypersensitivity to the active substance or to murine proteins, or to any of the other excipients listed in section 6.1.~~
~~Active, severe infections (see section 4.4). Patients in~~

~~a severely immunocompromised state.~~

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4.4 Special warnings and precautions for use

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Excipients: ~~This medicinal product contains 2.3 mmol (or 52.6 mg) sodium per 10 mL vial and 11.5 mmol (or 263.2 mg) sodium per 50 mL vial. To be taken into consideration by patients on a controlled sodium diet.~~

This medicinal product contains 2.3 mmol (or 52.6 mg) sodium per 10 mL vial and 11.5 mmol (or 263.2 mg) sodium per 50 mL vial, equivalent to 2.6% (for 10 mL vial) and 13.2% (for 50 mL vial) of the WHO recommended maximum daily intake of 2 g sodium for an adult.

This medicinal product contains 7.0 mg of polysorbate 80 (E 433) per 10 mL vial and 35.0 mg of polysorbate 80 (E 433) per 50 mL vial, which is equivalent to 0.7 mg/mL. Polysorbates may cause allergic reactions.

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4.8 Undesirable effects

Maintenance treatment (GPA/PA Study2)

In GPA/MPA Study 2, a total of 57 severe, active GPA and MPA were treated with rituximab for the maintenance of remission (see section 5.1).

Table 4 Adverse reactions occurring in ≥ 5% of patients receiving rituximab in GPA/MPA Study 2 (Rituximab n=57), and at a higher frequency than the comparator group, or during postmarketing surveillance.

~~MedDRA System Organ Class~~ ~~Adverse reaction~~	~~Frequency~~
~~Infections and infestations~~	
~~Bronchitis~~	~~14%~~
~~Rhinitis~~	~~5%~~
~~Serious viral infection[1]~~	~~not known~~
~~General disorders and administration site conditions~~	
~~Pyrexia~~	~~9%~~
~~Influenza-like illness~~	~~5%~~
~~Oedema peripheral~~	~~5%~~
~~Gastrointestinal disorders~~	
~~Diarrhoea~~	~~7%~~
~~Respiratory, thoracic and mediastinal disorders~~	
~~Dyspnoea~~	~~9%~~
~~Injury, poisoning and procedural complications~~	
~~Infusion-related reactions[2]~~	~~12%~~
~~[1] Observed during postmarketing surveillance. See also section infections below.~~ ~~[2] Details on infusion related reactions are provided in the description of selected adverse drug reactions section.~~	

MedDRA System organ class	Very common	Common	Not known
Infections and infestations	bronchitis	rhinitis	serious viral infection[1],[2] enteroviral meningoencephalitis[1]
Respiratory, thoracic and mediastinal disorders	-	dyspnoea	-
Gastrointestinal disorders	-	diarrhoea	-
General disorders and administration site conditions	-	pyrexia, influenza-like illness, oedema peripheral	-
Injury, poisoning and procedural complications	infusion-related reactions[3]	-	-

[1] Observed during post-marketing surveillance.
[2] See also section infections below.
[3] Details on infusion-related reactions are provided in the description of selected adverse reactions section.

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5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: antineoplastic agents, monoclonal antibodies and antibody drug conjugated,
ATC code: L01FA01~~L01X C02~~