

אוגוסט 2024



רופא/ה נכבד/ה,

רוקח/ת נכבד/ה,

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

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

המרכיב הפעיל הינו: rituximab 10mg/ml

ההתוויות הרשומות לתכשיר בישראל הינו:

Rixathon is indicated for the following indications:

*** Non-Hodgkin's lymphoma (NHL):**

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.

*** Chronic lymphocytic leukaemia (CLL):**

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.

*** Granulomatosis with polyangiitis and Microscopic polyangiitis:**

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).

*** Pemphigus vulgaris (PV):**

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

*Rheumatoid arthritis

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.

מהות השינוי: הוספת תנאי אחסון in-use אלטרנטיביים של 7 ימים בטמפרטורה של עד 30°C, כשהתכשיר מוגן מאור.

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות:

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

לעדכוןכם בברכה,

מגר' דפנה סנדובסקי

רוקחת ממונה

סנדוז פרמצבטיקה ישראל בע"מ

השינויים בעלון לרופא:

6.3 Shelf life

Unopened vial:

The expiry date of the product is indicated on the packing materials.

Rixathon may be stored at temperatures up to a maximum of 30°C for a single period of up to 7 days, but not exceeding the original expiry date. The new expiry date must be written on the carton. Upon removal from refrigerated storage, Rixathon must not be returned to refrigerated storage.

Diluted solution

• After aseptic dilution in sodium chloride solution:

Chemical and physical stability of Rixathon diluted in 0.9% sodium chloride solution has been demonstrated for:

- -30 days at 2°C - 8°C and subsequently 24 hours at room temperature ($\leq 25^\circ\text{C}$).

Or

- 7 days at $\leq 30^\circ\text{C}$, while protected from light.

• After aseptic dilution in glucose solution:

Chemical and physical stability of Rixathon diluted in 5% glucose solution has been demonstrated for 24 hours at 2°C - 8°C and subsequently 12 hours at room temperature ($\leq 25^\circ\text{C}$).

From a microbiological point of view, the prepared infusion solution should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of

the user and would normally not be longer than 24 hours at 2°C – 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

