11/2025

Ultomiris 100 mg/ml

אולטומיריס 100 מ"ג למ"ל

RAVULIZUMAB 100 MG/ML

CONCENTRATE FOR SOLUTION FOR INFUSION

רופא /ה, רוקח/ת נכבד
חברת אלקסיון פארמה ישראל בע"מ מבקשת להודיע על עדכון העלון לרופא של התכשיר שבנידון.
העלון עודכן בתאריך 11/2025.

ההתוויה הרשומה לתכשיר בישראל:

• Ultomiris is indicated in the treatment of adult and paediatric patients with a body weight of 10 kg or above with paroxysmal nocturnal haemoglobinuria (PNH):
* In patients with haemolysis with clinical symptom(s) indicative of high disease activity.
* In patients who are clinically stable after having been treated with eculizumab for at least the past 6 months.
• Ultomiris is indicated in the treatment of patients with a body weight of 10 kg or above with atypical haemolytic uremic syndrome aHUS who are complement inhibitor treatment naïve or have received eculizumab for at least 3 months and have evidence of response to eculizumab.
• Ultomiris is indicated in the treatment of adult patients with generalized myasthenia gravis (gMG) who are antiacetylcholine receptor (AChR) antibody-positive.
• Ultomiris is indicated in the treatment of adult patients with neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin 4 (AQP4) antibody-positive.

עדכון העלון כולל הסרה של מינון Ultomiris 10mg/ml לכל אורך העלון, זאת לאור הפסקת שיווק וביטול רישום של מינון זה.

בנוסף, להלן עדכונים עיקריים נוספים שחלו בעלון לרופא:

מידע שהוסר -מסומן בקו אדום חוצה ~~XXX~~
תוספת -כתב **כחול**

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Ultomiris 300 mg/3 mL concentrate for solution for infusion
(…)
Excipient(s) with known effect:
Sodium (4.6 mg per 3 mL vial), **polysorbate 80 (1.5 mg per vial)**

Ultomiris 1,100 mg/11 mL concentrate for solution for infusion
(…)
Excipient(s) with known effect:
Sodium (16.8 mg per 11 mL vial), **polysorbate 80 (5.5 mg per vial)**

ניאופרם (ישראל) 1996 בע"מ בנין ניאופרם, רח' השילוח 6 ת.ד. 7063 פתח תקוה 4917001
Email: neopharm@neopharmisrael.com פקס: 03-9373716 טל: 03-9373737 www.neopharmgroup.com

3. PHARMACEUTICAL FORM

(…)

Translucent, clear to yellowish colour, pH 7.4 solution **and osmolality of approximately 250 – 350 mOsm/kg**.

4.4 Special warnings and precautions for use

(…)

Serious meningococcal infection

(…)

Vaccines against **all available** serogroups **including** A, C, Y, W135 and B ~~**where available**~~, are recommended in preventing the commonly pathogenic meningococcal serogroups. Patients must be vaccinated ~~**or**~~ **and** revaccinated according to current national guidelines for vaccination use.

(…)

Patients should be informed of these signs and symptoms and steps should be taken to seek medical care immediately. Physicians should provide patients with a Patient ~~**information brochure**~~ **guide** and a Patient card.

(…)

Polysorbate 80 content

This medicinal product contains 1.5 mg of polysorbate 80 in each 3 mL vial and 5.5 mg in each 11 mL vial, which is equivalent to 0.53 mg/kg or less at the maximum dose for adult patients and paediatric patients with body weight more than 10 kg. Polysorbates may cause allergic reactions

4.6 Fertility, pregnancy and lactation

Women of childbearing potential

Women of childbearing potential should use effective contraception methods during treatment and ~~**up to**~~ **for** 8 months after treatment.

4.8 Undesirable effects

Summary of the safety profile

The most common adverse reactions with ravulizumab are headache (30.**6**%), upper respiratory tract infection (21.~~**1**~~**6**%), nasopharyngitis (20.~~**1**~~**4**%), diarrhoea (18.~~**1**~~**7**%), pyrexia (17.~~**6**~~**7**%), nausea (~~**14.6**~~**15**%), arthralgia (14.~~**1**~~**4**%), back pain (13.~~**5**~~**6**%), fatigue (13.~~**1**~~**3**%), abdominal pain (12.3%), dizziness (10.~~**5**~~**7**%) and urinary tract infection (10.~~**2**~~**7**%). The most serious adverse reactions are meningococcal infection (0.7%) including meningococcal sepsis, **meningococcal meningitis**, encephalitis meningococcal, meningococcal infection (see section 4.4) and disseminated gonococcal infection (0.2%) **including disseminated gonococcal infection and gonococcal infection**.

5.1 Pharmacodynamic properties

(…)

Study in adult patients with NMOSD

(…)

The primary endpoint of Study ALXN1210-NMO-307 was the time to first adjudicated on-trial relapse as determined by an independent adjudication committee. No adjudicated on-trial relapse was observed in ravulizumab-treated patients during the primary treatment period. All ravulizumab-treated patients remained relapse free over the median follow-up of 90.93 weeks. Ravulizumab-treated patients experienced

consistent relapse-free primary endpoint result with or without concomitant IST treatment.
In the final efficacy analysis with median follow up of 170.29 weeks, no adjudicated on-trial relapses were observed in ravulizumab treated patients through the end of study. Ravulizumab treatment responses observed during the Primary Evaluation Period were maintained throughout the duration of the study. In addition, among the 27 patients on IST treatment at Baseline, 17 (63%) had a decrease or stopped at least one IST therapy during treatment with ravulizumab.

לתשומת ליבכם כי קיימים בעלון עדכונים מינוריים נוספים שאינם משוקפים בהודעה זו.
למידע נוסף יש לעיין בעלון לרופא המעודכן.

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על ידי פניה לבעל הרישום (אלקסיון פארמה ישראל בע"מ, ת.ד. 7063, פתח תקווה 4917001; טלפון: 03-9373753 ; פקס: 03-9373774)

בברכה,
עוז וולך הרוקח הממונה של בעל הרישום