10/2024

Ultomiris 100 mg/ml

אולטומיריס 100 מ"ג למ"ל

RAVULIZUMAB 100 MG/ML

CONCENTRATE FOR SOLUTION FOR INFUSION

Ultomiris 10 mg/ml

אולטומיריס 10 מ"ג למ"ל

RAVULIZUMAB 10 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 08/2024.

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.

בהודעה זו מצוינים עדכוני בטיחות בלבד בעלון לרופא:

מידע שהוסר -מסומן בקו אדום חוצה ~~XXX~~

תוספת -כתב כחול

תוספת חמרה - כתב כחול -מסומן בצהוב מרקר

מידע שעבר מקום - כתב ירוק

4.8 Undesirable effects

The most common adverse reactions with ravulizumab are headache (~~28.2~~ 30%), upper respiratory tract infection (~~19.9~~ 21.1%), nasopharyngitis (~~19.5~~ 20.1%), diarrhoea (~~16.9~~ 18.1%), pyrexia (~~16.4~~ 17.6%), nausea (~~13.7~~ 14.6%), arthralgia (~~13.2~~ 14.1%), ~~fatigue (13.1%),~~ back pain (~~12.6~~ 13.5%), fatigue (13.1%), abdominal pain (~~11.8~~ 12.3%) ~~and~~, dizziness (~~10.1~~ 10.5%) and urinary tract infection (10.2%). The most serious adverse reactions are meningococcal infection (~~0.6~~ 0.7%) including meningococcal sepsis, encephalitis meningococcal, meningococcal infection (see section 4.4) and disseminated gonococcal infection (~~0.1~~ 0.2%).

Tabulated list of adverse reactions

(…)

Table 8: Adverse Drug reactions from clinical trials and postmarketing experience

MedDRA System Organ Class	Very common (≥ 1/10)	Common (≥ 1/100 to < 1/10)	Uncommon (≥ 1/1,000 to < 1/100)
Infections and infestations	Urinary tract infection [a] Upper respiratory tract infection,	~~Urinary tract infection~~	Meningococcal infection [~~a~~b], Disseminated Gonococcal infection [~~b~~c]

	Nasopharyngitis		
Immune system disorders		Hypersensitivity [de]	Anaphylactic reaction [ed]
Nervous system disorders	Dizziness, Headache ~~Dizziness~~	~~Dizziness~~	
Gastrointestinal disorders	Diarrhoea, Nausea, Abdominal pain	Vomiting, Dyspepsia	
Skin and subcutaneous tissue disorders		Urticaria, Pruritus, Rash	
Musculoskeletal and connective tissue disorders	Arthralgia, Back pain	Myalgia, Muscle spasms	
General disorders and administration site conditions	Pyrexia, Fatigue	Influenza like illness, Chills, Asthenia	
Injury, poisoning and procedural complications		Infusion-related reaction	

[a] Urinary tract infection is a group term that includes Preferred Terms: Urinary tract infection, Urinary tract infection bacterial, Urinary tract infection enterococcal, and Escherichia urinary tract infection

[b] Meningococcal infection includes preferred terms of meningococcal infection, meningococcal sepsis, and encephalitis meningococcal

~~[b]~~[c] Disseminated gonococcal infection includes preferred terms of disseminated gonococcal infection and gonococcal infection

~~[c]~~[d] Estimated from post-marketing experience

~~[d]~~[e] Hypersensitivity is a group term for Preferred Term drug hypersensitivity with related causality and Preferred Term hypersensitivity

(…)

Atypical haemolytic uremic syndrome (aHUS)

In paediatric patients with evidence of aHUS (N=34, aged 10 months to less than 18 years) included in ALXN1210-aHUS-312 study, the safety profile of ravulizumab appeared similar to that observed in adult patients with evidence of aHUS. The safety profiles in the different paediatric subsets of age appear similar. The safety data for patient below 2 years of age is limited to four patients. The most common adverse reactions (≥ 20%) reported in paediatric patients ~~was~~ were pyrexia, vomiting, diarrhoea, headache, nasopharyngitis, upper respiratory tract infection and abdominal pain ~~(32.3%)~~.

קיימים בעלון עדכונים נוספים, 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