10.2025

SOLIRIS
סוליריס

ECULIZUMAB
Concentrate for solution for infusion IV

רופא/ה ,רוקח/ת נכבד/ה,

חברת אלקסיון פארמה ישראל בע"מ מבקשת להודיע על עדכון העלון לרופא של התכשיר שבנידון.

ההתוויה הרשומה לתכשיר בישראל:

Soliris is indicated for the treatment of patients with:
-Paroxysmal nocturnal haemoglobinuria (PNH). Evidence of clinical benefit is demonstrated in patients with haemolysis with clinical symptom(s) indicative of high disease activity, regardless of transfusion history. Eculizumab has not been studied in clinical trials in patients with PNH below 11 years of age.
-Atypical haemolytic uremic syndrome (aHUS).
- Refractory generalized myasthenia gravis (gMG) in patients aged 6 years and above who are antiacetylcholine receptor (AChR) antibody-positive

Soliris is indicated in adults for the treatment of:
-Neuromyelitis optica spectrum disorder (NMOSD) in patients who are anti-aquaporin-4 (AQP4) antibodypositive with a relapsing course of the disease who have received prior therapy

בהודעה זו מצוינים העדכונים המהותיים בעלון לרופא
מידע שהוסר – מסומן ב~~קו אדום חוצה~~ ; תוספת – כתב כחול ;
טקסט שזז בצבע ירוק ; עדכון בטיחות – מסומן ברקע צהוב

3. PHARMACEUTICAL FORM
(…)
Clear, colorless, pH 7.0 solution **and osmolality of approximately 290-310 mOsm/kg.**

4.4 Special warnings and precautions for use
(…)
Meningococcal Infection
Due to its mechanism of action, the use of Soliris increases the patient's susceptibility to meningococcal infection (*Neisseria meningitidis*). Meningococcal disease due to any serogroup may occur. To reduce the risk of infection, all patients must be vaccinated at least 2 weeks prior to receiving Soliris, unless the risk of delaying Soliris therapy outweighs the risks of developing a meningococcal infection. Patients who initiate Soliris treatment less than 2 weeks after receiving a tetravalent meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Vaccines against **all available** serogroups **including** A, C, Y, W 135 **and B**, are recommended in preventing the commonly pathogenic meningococcal serogroups. ~~**Vaccine against serogroup B where available is also recommended**~~. Patients must ~~**receive vaccination**~~ **be vaccinated and revaccinated** according to current national ~~**vaccination**~~ guidelines for vaccination use.
(…)
Vaccination may not be sufficient to prevent meningococcal infection. Consideration should be given to official guidance on the appropriate use of antibacterial agents. Cases of serious or fatal meningococcal infections have been reported in Soliris-treated patients. Sepsis is a common presentation of meningococcal infections in patients treated with Soliris (see section 4.8). All patients should be monitored for early signs of meningococcal infection, evaluated immediately if infection is suspected, and treated with appropriate antibiotics if necessary. Patients should be informed of these signs and symptoms and steps taken to seek

medical care immediately. Physicians must discuss the benefits and risks of Soliris therapy with patients and provide them with a **Patient guide** ~~**patient information brochure**~~ and a patient ~~**safety**~~ card.
(…)

Immunization
Prior to initiating Soliris therapy, it is recommended that PNH, aHUS, refractory gMG and NMOSD patients initiate immunizations according to current immunization guidelines. Additionally, all patients must be vaccinated against meningococcal infections at least 2 weeks prior to receiving Soliris unless the risk of delaying Soliris therapy outweighs the risks of developing a meningococcal infection. Patients who initiate Soliris treatment less than 2 weeks after receiving a tetravalent meningococcal vaccine must receive treatment with appropriate prophylactic antibiotics until 2 weeks after vaccination. Vaccines against **all available** serogroups **including** A, C, Y, W 135 **and B** are recommended in preventing the commonly pathogenic meningococcal serogroups. ~~**Vaccine against serogroup B where available is also recommended**~~ **Patients must be vaccinated and revaccinated according to current national guidelines for vaccination use** (see Meningococcal Infection).
(…)

Educational materials
All physicians who intend to prescribe Soliris must ensure they are familiar with the ~~**physician's**~~ guide **for Healthcare Professionals** to prescribing. Physicians must discuss the benefits and risks of Soliris therapy with patients and provide them with a **Patient guide** ~~**patient information brochure**~~ and a patient ~~**safety**~~ card.

4.8 Undesirable effects

(…)
Tabulated list of adverse reactions
Table 1 gives the adverse reactions observed from spontaneous reporting and in eculizumab completed clinical trials, including PNH, aHUS, refractory gMG and NMOSD studies. Adverse reactions reported at a very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100) or rare (≥1/10,000 to <1/1,000) ~~**frequency with eculizumab, are listed by system organ class and preferred term. Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness**~~ **or not known (cannot be estimated from the available data) frequency with eculizumab, are listed by system organ class and preferred term. Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness**.

(…)

MedDRA System Organ Class	**Very Common (≥1/10)**	**Common (≥1/100 to <1/10)**	**Uncommon (≥1/1,000 to <1/100)**	**Rare (≥1/10,000 to <1/1,000)**	**Not known (cannot be estimated from the available data)**
(…)					
Hepatobiliary disorders			Alanine aminotransferase increased, Aspartate aminotransferase increased, Gamma-glutamyltransferase increased	Jaundice	**Liver injury**[d]
(…)					

Investigations			~~Alanine aminotransferase increased, Aspartate aminotransferase increased, Gamma-glutamyltransferase increased~~ Haematocrit decreased, Haemoglobin decreased	Coombs test positive[c]	

(…)

[d] **Frequency cannot be estimated from the available postmarketing data.**

קיימים בעלון עדכונים נוספים, למידע נוסף יש לעיין בעלון לרופא המעודכן.

העלון 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