12.2023

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).

Soliris is indicated in adults for the treatment of:
- Refractory generalized myasthenia gravis (gMG) in patients who are anti-acetylcholine receptor (AChR) antibody-positive.
- 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 בקו אדום חוצה
תוספת – כתב כחול
עדכון בטיחות – מסומן ברקע צהוב

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed. Based on the potential inhibitory effect of eculizumab on complement-dependent cytotoxicity of rituximab, eculizumab may reduce the expected pharmacodynamic effects of rituximab.

~~Chronic~~ Concomitant use of eculizumab with intravenous ~~human~~ immunoglobulin (IVIg) may reduce effectiveness of eculizumab. Closely monitor for reduced effectiveness of eculizumab.

Concomitant use of eculizumab with ~~treatment may interfere with the endosomal~~ neonatal Fc receptor (FcRn) blockers ~~recycling mechanism of monoclonal antibodies such as eculizumab and thereby decrease serum eculizumab concentrations~~ may lower systemic exposures and reduce effectiveness of eculizumab. Closely monitor for reduced effectiveness of eculizumab.

4.8 Undesirable effects

(…)

Table 1: Adverse Reactions reported in eculizumab clinical trials, including patients with PNH, aHUS, refractory gMG and NMOSD as well as from postmarketing experience

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)

Infection and infestations		Pneumonia, Upper respiratory tract infection, Bronchitis, Nasopharyngitis, Urinary tract infection, Oral Herpes	Meningococcal infection[b], Sepsis, Septic shock, Peritonitis, Lower respiratory tract infection, Fungal infection, Viral infection, Abscess[a], Cellulitis, Influenza, Gastrointestinal infection, Cystitis, Infection, Sinusitis, Gingivitis	Aspergillus infection[c], Arthritis bacterial[c], Genitourinary tract gonococcal infection, *Haemophilus influenzae* infection, Impetigo, ~~Gingivitis~~
(…)				
Psychiatric disorders		Insomnia	Depression, Anxiety, Mood swings, Sleep disorder	Abnormal dreams, ~~Sleep disorder~~
Nervous system disorders	Headache	Dizziness, ~~Dysgeusia~~	Paraesthesia, Tremor, Dysgeusia, Syncope	~~Syncope~~
(…)				
Skin and subcutaneous tissue disorders		Rash, Pruritus, Alopecia	Urticaria, Erythema, Petechiae, Hyperhidrosis, Dry skin, Dermatitis	~~Dermatitis~~, Skin depigmentation
Musculoskeletal and connective tissue disorders		Arthralgia, Myalgia, Pain in extremity	Muscle spasms, Bone pain, Back pain, Neck pain, ~~Joint swelling, Pain in extremity~~	Trismus, Joint swelling
(…)				
Injury, poisoning and procedural complication		Infusion related reaction	~~Infusion related reaction~~	

(…)

6.6 Special precautions for disposal and other handling

(…)

Prior to administration, the Soliris solution should be visually inspected for particulate matter and discolouration. Do not use if there is evidence of particulate matter or discolouration.

(…)

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

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בברכה,

עוז וולך הרוקח הממונה של בעל הרישום