Abbreviated Prescribing Information

Please refer to the SmPC for further information before prescribing.

Soliris® (eculizumab) 300 mg concentrate for solution for infusion. **ATC code:** L04AJ01.

Presentation: 30 ml vial containing 300 mg eculizumab (10 mg/ml).

Indications: Treatment of paroxysmal nocturnal haemoglobinuria (PNH) in adults and children; Evidence of clinical benefit is demonstrated in patients with haemolysis with clinical symptom(s) indicative of high disease activity, regardless of transfusion history. Treatment of atypical haemolytic uremic syndrome (aHUS) in adults and children. Treatment of refractory generalized myasthenia gravis (gMG) in patients age 6 years and above who are anti-acetylcholine receptor (AChR) antibody-positive. Treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody-positive with a relapsing course of the disease.

Posology and method of administration: **Posology Adults (≥18 years of age):** *PNH initial phase:* 600 mg every week for the first 4 weeks and *maintenance phase:* 900 mg for the fifth week followed by 900 mg every 14 ± 2 days. *Adults (≥18 years of age) aHUS, refractory gMG and NMOSD initial phase:* 900 mg every week for the first 4 weeks, and maintenance phase: 1200 mg for the fifth week, followed by 1200 mg every 14 ± 2 days. **Posology Paediatric Population:** The safety and efficacy of Soliris in children with refractory gMG aged less than 6 years old and in children with NMOSD aged less than 18 years old have not been established. *Paediatric patients with PNH, aHUS or refractory gMG with body weight ≥ 40 kg:* treat in accordance with the adult dosing recommendations. *Paediatric patients with PNH, aHUS or refractory gMG with body weight 30 - <40 kg*: initial phase of 600 mg weekly for the first 2 weeks, followed by a maintenance phase of 900 mg at week 3; then 900 mg every 2 weeks. *Paediatric patients with PNH, aHUS or refractory gMG with body weight 20 - <30 kg:* initial phase of 600 mg weekly for the first 2 weeks, followed by a maintenance phase of 600 mg at week 3; then 600 mg every 2 weeks. *Paediatric patients with PNH, aHUS or refractory gMG with body weight 10 - <20 kg:* initial phase of 600 mg single dose at week 1, followed by a maintenance phase of 300 mg at week 2; then 300 mg every 2 weeks. *Paediatric patients with PNH, aHUS or refractory gMG with body weight 5 - <10 kg: i*nitial phase of 300 mg at week 1, followed by a maintenance phase of 300 mg at week 2; then 300 mg every 3 weeks. Soliris has not been studied in patients with PNH or refractory gMG who weigh less than 40kg. Please refer to the SmPC for further information. **Method of Administration:** Soliris is administered via a 25 – 45 minute (35 minutes ± 10 minutes) intravenous infusion. Do not administer as an intravenous push or bolus injection. The diluted solution of Soliris should be administered by intravenous infusion via gravity feed, a syringe-type pump, or an infusion pump. Supplemental dosing of Soliris is required in the setting of concomitant plasmapheresis (PP), plasma exchange (PE), fresh frozen plasma infusion (PI) or intravenous immunoglobulin (IVIg) treatment (please refer to the SmPC for further information). **Contraindications:** Hypersensitivity to eculizumab, murine proteins or to any of the excipients; in patients with unresolved *Neisseria meningitidis* infection; in patients who are not currently vaccinated against *Neisseria meningitidis* (unless they receive prophylactic treatment with appropriate antibiotics until 2 weeks after vaccination. **Special warnings and precautions for use: Traceability:** To improve traceability, the batch number of Soliris should be recorded. **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 serogroups A, C, Y, W 135 are recommended. Vaccine against serogroup B where available is also recommended. Patients must receive vaccination according to current national vaccination guidelines. Vaccination may further activate complement. As a result, patients with PNH, aHUS, refractory gMG and NMOSD, may experience increased signs and symptoms of their underlying disease, such as haemolysis (PNH), TMA (aHUS), MG exacerbation (refractory gMG) or relapse (NMOSD). Patients should be closely monitored for disease symptoms after recommended vaccination. 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. 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 information brochure and a patient safety card. **Other System Infections:** Due to its mechanism of action, Soliris therapy should be administered with caution to patients with active systemic infections. Patients may have increased susceptibility to infections, especially with *Neisseria* and encapsulated bacteria. **Infusion Reactions:** Administration of Soliris may result in infusion reactions or immunogenicity that could cause allergic or hypersensitivity reactions (including anaphylaxis). Treatment should be interrupted in all patients experiencing severe infusion reactions and appropriate medical therapy administered. **Monitoring:** *Refractory gMG:* when immunosuppressant and anticholinesterase therapies are decreased or discontinued, patients should be monitored closely for signs of disease exacerbation. *NMOSD*: when immunosuppressant therapy is decreased or discontinued, patients should be monitored closely for signs and symptoms of potential NMOSD relapse. *PNH patients*: receiving Soliris therapy should be monitored for intravascular haemolysis by measuring LDH levels and may require dose adjustment within the recommended 14±2 day dosing schedule during the maintenance phase (up to every 12 days). PNH Patients who discontinue treatment with Soliris should be monitored for signs and symptoms of serious intravascular haemolysis for at least 8 weeks. *aHUS patients* receiving Soliris therapy should be monitored for thrombotic microangiopathy by measuring platelet counts, serum LDH and serum creatinine, and may require dose adjustment within the recommended 14±2 day dosing schedule during the maintenance phase (up to every 12 days). If aHUS patients discontinue treatment with Soliris, they should be monitored closely for signs and symptoms of severe thrombotic microangiopathy complications. Monitoring may be insufficient to predict or prevent severe thrombotic microangiopathy complications in patients with aHUS after discontinuation of Soliris. Use of Soliris in refractory gMG and NMOSD treatment has been studied only in the setting of chronic administration. Patients who discontinue Soliris treatment should be carefully monitored for signs and symptoms of disease gMG exacerbation or potential NMOSD relapse. **Sodium content:** Once diluted with sodium chloride 9 mg/mL (0.9%) solution for injection, this medicinal product contains 0.88 g sodium per 240 mL at the

maximal dose, equivalent to 44.0% of the WHO recommended maximum daily intake of 2 g sodium for an adult. Once diluted with sodium chloride 4.5 mg/mL (0.45%) solution for injection, this medicinal product contains 0.67 g sodium per 240 mL at the maximal dose, equivalent to 33.5% of the WHO recommended maximum daily intake of 2 g sodium for an adult. **Interaction with other medicinal products and other forms of interaction:** No interaction studies have been performed. Plasma exchange (PE), plasmapheresis (PP), fresh frozen plasma infusion (PI) and intravenous immunoglobulin (IVIg) have been shown to reduce eculizumab serum levels. A supplemental dose of eculizumab is required in these settings. Concomitant use of eculizumab with intravenous immunoglobulin (IVIg) may reduce effectiveness of eculizumab. Concomitant use of eculizumab with neonatal Fc receptor (FcRn) blockers may lower systemic exposures and reduce effectiveness of eculizumab. Closely monitor for reduced effectiveness of eculizumab. **Fertility, Pregnancy and Lactation:** Women of childbearing potential have to use effective contraception during treatment and up to 5 months after treatment. No effects on the breastfed newborn / infant are anticipated as limited data available suggest that eculizumab is not excreted in human breast milk. **Undesirable effects:** The most common adverse reactions were headache, and the most serious adverse reaction was meningococcal infection. *Very common adverse reactions (≥1/10):* headache. Common adverse reactions (≥1/100 to <1/10): Pneumonia, Upper respiratory tract infection, Bronchitis, Nasopharyngitis, Urinary tract infection, Oral Herpes Leukopenia, Anaemia, Insomnia, Dizziness, Hypertension, Cough, Oropharyngeal pain, Diarrhoea, Vomiting, Nausea, Abdominal pain, Rash, Alopecia, Pruritus, Arthralgia, Myalgia, Pain in extremity, Pyrexia, Fatigue, Influenza like illness, Infusion-related reaction. Please refer to the SmPC for a full list of undesirable effects. **Storage:** 2°C – 8°C. **Alexion Local Representative:** Alexion Pharma Nordics AB, Puh/Tel: +46 0 8 557 727 50 **Only for NO: Prescription group C. Reimbursement:** H prescription. L04A J01_1 Ekulizumab. **Price (2024-03-06):** 1 vial: 300 mg/30 ml, 53835,90 NOK. **Only for SE: Prescription group:** Rx. **Reimbursement:** EF. **Only for FI:** Prescription medicine. **Reimbursement:** No. **Price (2024-03-06):** 1 vial**:** 300 mg/3 ml, 5262,31 EUR. **Only for DK**: **Dispensing group:** BEGR. **Reimbursement:** No. **Marketing Authorization Holder:** Alexion Europe SAS, 103-105 rue Anatole France, 92300 Levallois-Perret, FRANCE. **Further Information available from**: Alexion Pharmaceuticals e-mail: MedInfo.EMEA@alexion.com **SmPC was last revised:** July 2023. Soliris® is a registered trademark of Alexion Pharmaceuticals, Inc. For actual price and detailed information on this medicinal product, please see, www.felleskatalogen.no (NO), www.fass.se (SE), www.pharmacafennica.fi (FI), www.medicinpriser.dk (DK), http://www.ema.europa.eu (EU).

Adverse Event Reporting

Please report any adverse events via your national reporting system. Adverse events can also be reported to Alexion Pharmaceuticals by contacting: https://contactazmedical.astrazeneca.com/